17 August 2020
EMA/CHMP/365761/2020
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Minutes for the meeting on 25-28 May 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

Disclaimers

Some of the information contained in the minutes is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the CHMP meeting highlights once the procedures are finalised and start of referrals will also be available.

Of note, the minutes are a working document primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

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1. Introduction

1.1. Welcome and declarations of interest of members, alternates and experts

The participants had no objection to hold the meeting remotely.

In accordance with the Agency's policy on handling of declarations of interests of scientific Committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the current meeting, the Committee Secretariat announced the restricted involvement of some meeting participants in upcoming discussions as included in the pre-meeting list of participants and restrictions. See (current) May 2020 CHMP minutes for the list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session held 25-28 May 2020 (to be published post June 2020 CHMP meeting).

Participants in this meeting were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure and as included in the list of participants. All decisions taken at this meeting were made in the presence of a quorum of members (i.e. 17 or more members were present remotely). All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

1.2. Adoption of agenda

CHMP agenda for 25-28 May 2020

The CHMP adopted the agenda.

1.3. Adoption of the minutes

CHMP minutes for 28-30 April 2020

The CHMP adopted the minutes.

ORGAM minutes for 18 May 2020

The Minutes of the May 2020 CHMP ORGAM meeting held on 18 May 2020, together with all decisions taken at that meeting, were adopted.

Extraordinary CHMP meeting on remdesivir, 15 May 2020

The minutes of the extraordinary meeting were adopted.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. bevacizumab - EMEA/H/C/005106

treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer and recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer.
First-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer.
First line treatment of patients with advanced and/or metastatic renal cell cancer.

Scope: Possible Oral Explanation/List of Outstanding Issues

Action: Possible oral explanation to be held on Monday, 25 May 2020 at 16:00

List of Outstanding Issues adopted on 26.03.2020. List of Questions adopted on 14.11.2019.

The CHMP agreed that no oral explanation is needed at this time.

See 3.2

2.1.2. Hepcludex - bulevirtide - Orphan - EMEA/H/C/004854

MYR GmbH; indicated for the treatment of chronic hepatitis delta virus (HDV) infection in adult patients with compensated liver disease.

Scope: Possible Oral Explanation/Opinion

Draft list of experts for the ad-hoc expert group meeting scheduled on 20 May 2020 - adopted via written procedure on 20 May 2020, AHEG Report

Action: Possible oral explanation to be held on Wednesday, 27 May 2020 at 09:00

New active substance (Article 8(3) of Directive No 2001/83/EC)

List of Outstanding Issues adopted on 24.03.2020. List of Questions adopted on 28.01.2020.

The CHMP agreed that no oral explanation is needed at this time.

See 3.1

2.1.3. Rozlytrek - entrectinib - EMEA/H/C/004936

Roche Registration GmbH; treatment of adult and paediatric patients with neurotrophic tyrosine receptor kinase (NTRK) fusion-positive locally advanced or metastatic solid tumours and treatment of patients with ROS1-positive, advanced non-small cell lung cancer (NSCLC).

Scope: Possible Oral Explanation/Opinion

Action: Possible oral explanation to be held on Wednesday, 27 May 2020 at 15:30

New active substance (Article 8(3) of Directive No 2001/83/EC)

List of Outstanding Issues adopted on 12.12.2019, 17.10.2019. List of Questions adopted on 29.05.2019.

The CHMP agreed that no oral explanation is needed at this time.

See 3.1

2.1.4. pexidartinib - Orphan - EMEA/H/C/004832

Daiichi Sankyo Europe GmbH; treatment of adult patients with symptomatic tenosynovial giant cell tumour (TGCT), also referred to as giant cell tumour of the tendon sheath (GCT-TS) or pigmented villonodular synovitis (PVNS).

Scope: Oral explanation

Action: Oral explanation to be held on Tuesday, 26 May 2020 at 14:00

List of Outstanding Issues adopted on 26.03.2020, 12.12.2019. List of Questions adopted on 25.07.2019.

An oral explanation was held on Tuesday, 26 May 2020. The presentation by the applicant focused on the clinical efficacy and safety data in support of the application.

2.1.5. Xenleta - lefamulin - EMEA/H/C/005048

Nabriva Therapeutics Ireland DAC; treatment of community-acquired pneumonia (CAP).

Scope: Possible Oral Explanation/Opinion

Action: Possible oral explanation to be held on Wednesday, 27 May 2020 at 11:00

New active substance (Article 8(3) of Directive No 2001/83/EC)

List of Outstanding Issues adopted on 26.03.2020. List of Questions adopted on 17.10.2019.

The CHMP agreed that no oral explanation is needed at this time.

See 3.1

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

2.3.1. Invokana - canagliflozin - EMEA/H/C/002649/II/0046

Janssen-Cilag International NV

Rapporteur: Martina Weise, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Martin Huber

Scope: "Update of sections 4.1 , 4.2, , 4.4, 4.8, 5.1 and 6.6 of the Summary of Product

Characteristics to modify the therapeutic indication for Invokana (canagliflozin) based upon new clinical efficacy and safety data from the Phase 3 study: Canagliflozin and Renal Events in Diabetes with Established Nephropathy Clinical Evaluation Trial (CREDENCE) (DNE3001). This study provides data on the use of Invokana in addition to standard of care in diabetic kidney disease patients. The Package Leaflet is updated accordingly. The RMP version 8.5 has also been agreed. In addition, the list of local representatives in the Package Leaflet has been revised. The variation leads to amendments to the Summary of Product Characteristics and Package Leaflet and to the Risk Management Plan (RMP)."

Possible oral explanation

Action: Possible oral explanation to be held on Tuesday, 26 May 2020 at 16:00

Request for Supplementary Information adopted on 30.04.2020, 27.02.2020, 14.11.2019.

The CHMP agreed that no oral explanation is needed at this time.

See 5.1

2.3.2. Lynparza - olaparib - EMEA/H/C/003726/II/0033

AstraZeneca AB

Rapporteur: Alexandre Moreau, Co-Rapporteur: Koenraad Norga, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension of indication to support the use of Lynparza tablets (100 mg and 150 mg) for the maintenance treatment of gBRCAm metastatic pancreatic cancer based on the results from the pivotal Phase 3 study, POLO; as a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to update section 4.8 for Lynparza hard capsules (50 mg) to revise the list of ADR based on the pooled safety data analysis. The RMP version 18 has also been submitted. Furthermore, the PI is brought in line with the latest guideline regarding the sodium content. The MAH also took the occasion to include some minor editorial changes in the PI.",

Possible oral explanation

Action: Possible oral explanation to be held on Monday, 25 May 2020 at 14:00

Request for Supplementary Information adopted on 30.04.2020, 30.01.2020, 17.10.2019.

An oral explanation was held on Monday, 25 May 2020. The presentation by the applicant focused on the clinical efficacy data in support of the application.

See 5.1

2.3.3. Xtandi - enzalutamide - EMEA/H/C/002639/II/0047/G

Astellas Pharma Europe B.V.

Rapporteur: Jorge Camarero Jiménez, PRAC Rapporteur: Eva A. Segovia

Scope: "C.1.6: Extension of indication to include the treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) for Xtandi in combination with androgen deprivation therapy; As a consequence, sections 4.1, 4.7, 4.8, 5.1, 5.3 and 6.6 of the SmPC are updated. Furthermore the MAH took the opportunity to make corrections to section 4.7.

The Package Leaflet is updated in accordance. The RMP version 13.0 has also been submitted.
C.1.4: Update of section 5.1 of the SmPC based the 5-year Overall Survival (OS) results obtained from the PREVAIL study (MDV310003), a phase 3 study of enzalutamide in chemotherapy naïve patients with metastatic prostate cancer that progressed on ADT.",

Oral explanation

Action: Oral explanation to be held on Tuesday, 26 May 2020 at 11:00

Request for Supplementary Information adopted on 17.10.2019.

An oral explanation was held on Tuesday, 26 May 2020. The presentation by the applicant focused on some aspects concerning the clinical study conduct .

See 5.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Apixaban Accord - apixaban - EMEA/H/C/005358

Accord Healthcare S.L.U.; prevention of venous thromboembolic events (VTE).

Scope: Opinion

Action: For adoption

Generic application (Article 10(1) of Directive No 2001/83/EC), Generic of Eliquis

List of Outstanding Issues adopted on 26.03.2020. List of Questions adopted on 17.10.2019.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to medical prescription.

The CHMP noted the letter of recommendation dated 27.05.2020.

The summary of opinion was circulated for information.

3.1.2. Hepcludex - bulevirtide - Orphan - EMEA/H/C/004854

MYR GmbH; indicated for the treatment of chronic hepatitis delta virus (HDV) infection in adult patients with compensated liver disease.

Scope: Opinion

Draft list of experts for the ad-hoc expert group meeting scheduled on 20 May 2020 - adopted via written procedure on 20 May 2020, AHEG Report

Action: Possible oral explanation to be held on Wednesday, 27 May 2020 at 09:00

New active substance (Article 8(3) of Directive No 2001/83/EC)

List of Outstanding Issues adopted on 24.03.2020. List of Questions adopted on 28.01.2020.

See 2.1

The CHMP agreed that no oral explanation is needed at this time.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a conditional marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that bulevirtide is a new active substance, as claimed by the applicant.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to restricted medical prescription.

The CHMP noted the letter of recommendation dated 28.05.2020.

The summary of opinion was circulated for information.

3.1.3. MVABEA - Ebola vaccine (rDNA, replication-incompetent) - EMEA/H/C/005343

Janssen-Cilag International N.V.; indicated for active immunisation for prevention of disease caused by Ebola virus.

Scope: Opinion

Action: For adoption

New active substance (Article 8(3) of Directive No 2001/83/EC)

List of Outstanding Issues adopted on 28.04.2020. List of Questions adopted on 25.02.2020.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation under exceptional circumstances by consensus together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that Ebola vaccine (MVA-BN-Filo [recombinant]) is a

new active substance, as claimed by the applicant.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to medical prescription.

The CHMP noted the letter of recommendation dated 25.05.2020.

The summary of opinion was circulated for information.

3.1.4. Piqray - alpelisib - EMEA/H/C/004804

Novartis Europharm Limited; in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor2 (HER2)-negative, locally advanced or metastatic breast cancer with a PIK3CA mutation after disease progression following endocrine therapy as monotherapy.

Scope: Opinion

Action: For adoption

New active substance (Article 8(3) of Directive No 2001/83/EC)

List of Outstanding Issues adopted on 27.02.2020, 19.09.2019. List of Questions adopted on 29.05.2019.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by majority (21 out of 29 votes) together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that alpelisib is a new active substance, as claimed by the applicant.

The Icelandic Member was in agreement with the CHMP recommendation, the Norwegian Member against.

The divergent position (Sol Ruiz, Maria Concepcion Prieto Yerro, Christophe Focke, Alexandre Moreau, Bruno Sepodes, Kristina Dunder, Johann Lodewijk Hillege, John Joseph Borg, Bjorg Bolstad) was appended to the opinion.

The legal status was agreed as medicinal product subject to restricted medical prescription.

The summary of opinion was circulated for information.

3.1.5. Rozlytrek - entrectinib - EMEA/H/C/004936

Roche Registration GmbH; treatment of adult and paediatric patients with neurotrophic tyrosine receptor kinase (NTRK) fusion-positive locally advanced or metastatic solid tumours and treatment of patients with ROS1-positive, advanced non-small cell lung cancer (NSCLC).

Scope: Opinion

Action: For adoption

New active substance (Article 8(3) of Directive No 2001/83/EC)

List of Outstanding Issues adopted on 12.12.2019, 17.10.2019. List of Questions adopted on 29.05.2019.

See 2.1

The CHMP agreed that no oral explanation is needed at this time.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a conditional marketing authorisation by majority (25 out of 28 votes) together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that entrectinib is a new active substance, as claimed by the applicant.

The Icelandic Member was in agreement with the CHMP recommendation, the Norwegian Member against.

The divergent positions (Johann Lodewijk Hillege, Jan Mueller-Berghaus, Martina Weise) were appended to the opinion.

The legal status was agreed as medicinal product subject to restricted medical prescription.

The CHMP noted the letter of recommendation dated 28.05.2020.

The summary of opinion was circulated for information

3.1.6. Xenleta - lefamulin - EMEA/H/C/005048

Nabriva Therapeutics Ireland DAC; treatment of community-acquired pneumonia (CAP).

Scope: Opinion

Action: For adoption

New active substance (Article 8(3) of Directive No 2001/83/EC)

List of Outstanding Issues adopted on 26.03.2020. List of Questions adopted on 17.10.2019.

See 2.1

The CHMP agreed that no oral explanation is needed at this time.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that lefamulin is a new active substance, as claimed by the applicant.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to medical prescription.

The CHMP noted the letter of recommendation dated 28.05.2020.

The summary of opinion was circulated for information.

3.1.7. ZABDENO - Ebola vaccine (rDNA, replication-incompetent) - EMEA/H/C/005337

Janssen-Cilag International N.V.; indicated for active immunisation for prevention of disease caused by Ebola virus (Zaire ebolavirus species).

Scope: Opinion

Action: For adoption

New active substance (Article 8(3) of Directive No 2001/83/EC)

List of Outstanding Issues adopted on 28.04.2020. List of Questions adopted on 25.02.2020.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation under exceptional circumstances by consensus together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that Ebola vaccine (Ad26.ZEBOV-GP [recombinant]) is a new active substance, as claimed by the applicant.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to medical prescription.

The CHMP noted the letter of recommendation dated 25.05.2020.

The summary of opinion was circulated for information.

3.1.8. Zercepac - trastuzumab - EMEA/H/C/005209

Accord Healthcare S.L.U.; treatment of metastatic and early breast cancer and metastatic gastric cancer (MGC).

Scope: Opinion

Action: For adoption

Similar biological application (Article 10(4) of Directive No 2001/83/EC)

List of Outstanding Issues adopted on 26.03.2020. List of Questions adopted on 17.10.2019.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to medical prescription.

The CHMP noted the letter of recommendation dated 26.05.2020.

The summary of opinion was circulated for information.

3.2. Initial applications; List of outstanding issues (Day 180; Day 120 for procedures with accelerated assessment timetable)

3.2.1. abicipar pegol - EMEA/H/C/005103

Treatment of neovascular (wet) age-related macular degeneration (AMD).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.11.2019.

The Committee was reminded of the status of this application and its remaining outstanding issues

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.2. arsenic trioxide - EMEA/H/C/005218

Treatment of relapsed acute promyelocytic leukaemia (APL).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 12.12.2019.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.3. bevacizumab - EMEA/H/C/005106

Treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer and recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer.
First-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer.
First line treatment of patients with advanced and/or metastatic renal cell cancer.

Scope: List of Outstanding Issues

Action: For adoption

List of Outstanding Issues adopted on 26.03.2020. List of Questions adopted on 14.11.2019.

See 2.1

The CHMP agreed that no oral explanation is needed at this time.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a 2nd list of outstanding issues with a specific timetable.

3.2.4. bevacizumab - EMEA/H/C/005181

Treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer and recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer.
First-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer.
First line treatment of patients with advanced and/or metastatic renal cell cancer.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.01.2020.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.5. acalabrutinib - Orphan - EMEA/H/C/005299

AstraZeneca AB; treatment of adult patients with chronic lymphocytic leukaemia (CLL)/small lymphocytic lymphoma (SLL).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.02.2020.

The Committee was reminded of the status of this application and its remaining outstanding issues

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.6. satralizumab - Orphan - EMEA/H/C/004788

Roche Registration GmbH; treatment of adult and adolescent patients from 12 years of age with neuromyelitis optica spectrum disorders (NMOSD).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 10.12.2019.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues with a specific timetable.

3.2.7. fampridine - EMEA/H/C/005359

Treatment of Multiple Sclerosis.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 12.12.2019.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.8. filgotinib - EMEA/H/C/005113

Treatment of adult patients with moderately to severely active rheumatoid arthritis.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 12.12.2019.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.9. elexacaftor / tezacaftor / ivacaftor - Orphan - EMEA/H/C/005269

Vertex Pharmaceuticals (Ireland) Limited; treatment of cystic fibrosis.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 28.01.2020.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.10. teriparatide - EMEA/H/C/005087

Treatment of osteoporosis.

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 27.02.2020. List of Questions adopted on 19.09.2019.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a 2nd list of outstanding issues with a specific timetable.

The CHMP agreed to consult the BMWP and adopted a list of questions to this group.

3.2.11. caffeine citrate - EMEA/H/C/005435

Treatment of primary apnoea.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.02.2020.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.12. teriparatide - EMEA/H/C/005388

Treatment of osteoporosis.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.02.2020. List of Questions adopted on 19.09.2019.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a 2nd list of outstanding issues with a specific timetable.

The CHMP agreed to consult the BMWP and adopted a list of questions to this group.

3.2.13. rivaroxaban - EMEA/H/C/005279

Prevention of atherothrombotic events.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 12.12.2019.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues with a specific timetable.

3.2.14. deferiprone - Orphan - EMEA/H/C/005004

Apotex B.V.; treatment of neurodegeneration with brain iron accumulation

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.09.2019.

The Committee was reminded of the status of this application and its remaining outstanding issues

The Committee adopted a list of outstanding issues with a specific timetable.

3.3. Initial applications; List of questions (Day 120; Day 90 for procedures with accelerated assessment timetable)

3.3.1. bevacizumab - EMEA/H/C/005286

Treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer and recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer.
First-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer.
First line treatment of patients with advanced and/or metastatic renal cell cancer.

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

3.3.2. doxorubicin hydrochloride - EMEA/H/C/005330

Treatment of breast cancer, treatment of ovarian cancer, treatment of multiple myeloma, treatment of AIDS related Kaposi's sarcoma.

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

3.3.3. risperidone - EMEA/H/C/005406

Treatment of schizophrenia.

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

3.3.4. fedratinib - Orphan - EMEA/H/C/005026

Celgene Europe BV; treatment of primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

3.3.5. autologous peripheral blood T cells CD4 and CD8 selected and CD3 and CD28 activated transduced with retroviral vector expressing anti-CD19 CD28/CD3-zeta chimeric antigen receptor and cultured - Orphan - ATMP - EMEA/H/C/005102

Accelerated assessment

Kite Pharma EU B.V.; treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).

Scope: List of questions

Action: For information

The CHMP was updated on discussions at the CAT at their May meeting.

The Committee discussed the issues identified in this application.

The Committee endorsed the CAT recommendation and scientific discussion together with the list of questions.

3.3.6. lenalidomide - EMEA/H/C/005348

Treatment of multiple myeloma.

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

3.3.7. inclisiran - EMEA/H/C/005333

Treatment for primary hypercholesterolaemia or mixed dyslipidaemia.

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

3.3.8. ofatumumab - EMEA/H/C/005410

Treatment of relapsing forms of multiple sclerosis.

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

The CHMP agreed to consult the BSWP. The list of questions to the working party will be adopted after the meeting.

3.3.9. bevacizumab - EMEA/H/C/005556

Treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer and recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer.
First-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer.
First line treatment of patients with advanced and/or metastatic renal cell cancer.

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

3.3.10. pertuzumab / trastuzumab - EMEA/H/C/005386

Treatment of early breast cancer, metastatic breast cancer.

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

3.3.11. selpercatinib - EMEA/H/C/005375

Indicated for the treatment of adults with: advanced RET fusion-positive non-small cell lung cancer (NSCLC) who require systemic therapy; advanced RET fusion-positive thyroid cancer who require systemic therapy and who have progressed following prior treatment. As monotherapy is indicated for the treatment of adults and adolescents 12 years and older with advanced RET-mutant medullary thyroid cancer (MTC) who require systemic therapy.

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

3.3.12. tucatinib - EMEA/H/C/005263

Treatment of metastatic breast cancer or brain metastases.

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

3.3.13. eladocagene exuparvovec - Orphan - ATMP - EMEA/H/C/005352

PTC Therapeutics International Limited; treatment of aromatic L-amino aciddecarboxylase (AADC) deficiency.

Scope: List of questions

Action: For information

The CHMP was updated on discussions at the CAT at their May meeting.

The Committee discussed the issues identified in this application

The Committee endorsed the CAT recommendation and scientific discussion together with the list of questions.

3.3.14. obeticholic acid - EMEA/H/C/005249

Improvement of liver fibrosis and resolution of steatohepatitis in adult patients with significant liver fibrosis due to nonalcoholic steatohepatitis (NASH).

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

3.4. Update on on-going initial applications for Centralised procedure

3.4.1. amikacin - Orphan - EMEA/H/C/005264

Insmed Netherlands B.V.; treatment of lung infection as part of combination antibacterial drug regiment in adults.

Scope: Draft list of experts for the SAG on Anti-infectives meeting

Action: For adoption

List of Outstanding Issues adopted on 30.04.2020. List of Questions adopted on 14.11.2019.

The CHMP adopted the draft list of experts for the SAG anti-infectives meeting.

Nominations for additional experts should be sent.

3.4.2. azathioprine - EMEA/H/C/005055

Indicated for the prophylaxis of transplant rejection, and an immunosuppressant antimetabolite, indicated in patients who are intolerant to glucocorticosteroids, and chronic inflammatory bowel disease (IBD) (Crohn's disease or ulcerative colitis), relapsing multiple sclerosis, generalised myasthenia gravis.

Scope: Letter from the applicant dated 15 May 2020 requesting an extension of clock-stop to respond to the list of questions adopted in April 2020.

Action: For adoption

List of Questions adopted on 30.04.2020.

The CHMP agreed to the request by the applicant for an extension of clock-stop to respond to the list of questions adopted in April 2020.

3.4.3. idebenone - Orphan - EMEA/H/C/005123

Santhera Pharmaceuticals (Deutschland) GmbH; treatment of respiratory dysfunction in patients with Duchenne muscular dystrophy (DMD) not using glucocorticoids.

Scope: Letter from the applicant dated 13 May 2020 requesting an extension of clock-stop to respond to the list of outstanding issues adopted in April 2020 – adopted via written procedure on 14 May 2020.

Action: For information

Scope: Letter from the applicant dated 20 May 2020 requesting extension of clock-stop to respond to the list of outstanding issues adopted in April 2020.

Action: For adoption

List of Outstanding Issues adopted on 30.04.2020. List of Questions adopted on 17.10.2019.

The CHMP noted the extension to the clock stop adopted via written procedure and agreed to the request by the applicant for an additional extension of clock-stop to respond to the list of outstanding issues adopted in April 2020.

3.4.4. salmeterol xinafoate / fluticasone propionate - EMEA/H/C/004881

For treatment of asthma.

Scope: Letter from the applicant dated 11 May 2020 requesting an extension of clock-stop to respond to the list of questions adopted in February 2020.

Action: For adoption

List of Questions adopted on 27.02.2020.

The CHMP agreed to the request by the applicant for an extension of clock-stop to respond to the list of questions adopted in February 2020.

3.4.5. salmeterol xinafoate / fluticasone propionate - EMEA/H/C/005591

For treatment of asthma

Scope: Letter from the applicant dated 11 May 2020 requesting an extension of clock-stop to respond to the list of questions adopted in February 2020.

Action: For adoption

List of Questions adopted on 27.02.2020.

The CHMP agreed to the request by the applicant for an extension of clock-stop to respond to the list of questions adopted in February 2020.

3.4.6. lifitegrast - EMEA/H/C/004653

Treatment of moderate to severe dry eye disease in adults for whom prior artificial tears has not been sufficient.

Scope: Draft list of experts for the ad-hoc expert meeting scheduled on 11 June 2020

Action: For adoption

List of Outstanding Issues adopted on 12.12.2019. List of Questions adopted on 26.04.2019.

The CHMP adopted the list of experts for the ad-hoc expert meeting scheduled on 11 June 2020.

3.4.7. plazomicin - EMEA/H/C/004457

Treatment of complicated urinary tract infection (cUTI), including pyelonephritis; treatment of bloodstream infection (BSI); treatment of infections due to Enterobacteriaceae.

Scope: Letter from the applicant dated 15 May 2020 requesting an extension of clock-stop to respond to the list of outstanding issues adopted in November 2019.

Action: For adoption

List of Outstanding Issues adopted on 14.11.2019, 25.07.2019. List of Questions adopted on 28.02.2019.

The CHMP agreed to the request by the applicant for an extension of clock-stop to respond to the list of outstanding issues adopted in November 2019.

3.4.8. fostemsavir - EMEA/H/C/005011

Indicated, in combination with other antiretrovirals, for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a

suppressive anti-viral regimen due to resistance, intolerance or safety considerations.

Scope: Letter from the applicant dated 22 May 2020 requesting an extension of clock-stop to respond to the List of Questions adopted in April 2020.

List of Questions adopted on 28.04.2020.

The CHMP agreed to the request by the applicant for an extension of clock-stop to respond to the List of Questions adopted in April 2020.

3.4.9. sunitinib - EMEA/H/C/005419

Treatment of gastrointestinal stromal tumour (GIST) and metastatic renal cell carcinoma (MRCC) and pancreatic neuroendocrine tumours (pNET)

Scope: Letter from the applicant dated 21 May 2020 requesting an extension of clock-stop to respond to the List of Questions adopted in February 2020.**Action**: For adoption

List of Questions adopted on 27.02.2020.

The CHMP did not agree to the request by the applicant for an extension to the clock stop but to a shorter extension to respond to the List of Questions adopted in February 2020.

3.5. Re-examination of initial application procedures under Article 9(2) of Regulation no 726/2004

No items

3.6. Initial applications in the decision-making phase

3.6.1. Pretomanid FGK - pretomanid - Orphan - EMEA/H/C/005167

FGK Representative Service GmbH; treatment of tuberculosis

Scope: Letter from the EC on the opinion adopted in March 2020.

Action: For information

New active substance (Article 8(3) of Directive No 2001/83/EC)

Opinion adopted on 26.03.2020. List of Outstanding Issues adopted on 30.01.2020. List of Questions adopted on 25.07.2019.

The CHMP noted the letter from the EC.

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Erlotinib Accord - erlotinib - EMEA/H/C/005071

Accord Healthcare S.L.U.; treatment of lung and pancreatic cancers.

Scope: Withdrawal of initial marketing authorisation application

Action: For information

Generic application (Article 10(1) of Directive No 2001/83/EC), Generic of Tarceva

List of Outstanding Issues adopted on 26.03.2020, 29.05.2019. List of Questions adopted on 13.12.2018.

The CHMP noted the withdrawal of marketing authorisation application.

3.7.2. Fingolimod Mylan - fingolimod - EMEA/H/C/005282

Mylan Ireland Limited; treatment of multiple sclerosis.

Scope: Withdrawal of initial marketing authorisation application

Action: For information

Generic application (Article 10(1) of Directive No 2001/83/EC), Generic of Gilenya

List of Outstanding Issues adopted on 27.02.2020. List of Questions adopted on 19.09.2019.

The CHMP noted the withdrawal of marketing authorisation application.

4. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008

4.1. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Opinion

No items

4.2. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 180 list of outstanding issues

No items

4.3. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 120 List of question

4.3.1. Cosentyx - secukinumab - EMEA/H/C/003729/X/0059

Novartis Europharm Limited

Rapporteur: Tuomo Lapveteläinen, PRAC Rapporteur: Eva A. Segovia

Scope: "Extension application to add a new strength of 300 mg (in 2 ml) solution for injection (in pre-filled syringe and pre-filled pen). The RMP (version 7.0) is updated in accordance."

Action: For adoption

The Committee discussed the issues identified in this application, mainly concerning the new auto injector device and the comparability of the prefilled syringe and the new device

in terms of pharmacokinetics and safety.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

4.3.2. Nuceiva - botulinum toxin type A - EMEA/H/C/004587/X/0005

Evolus Pharma Limited

Rapporteur: Peter Kiely, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension application to add a new strength of 50 U for botulinum toxin type A for powder for solution for injection in vial (glass), for intramuscular administration."

Action: For adoption

The Committee discussed the issues identified in this application, concerning some quality issues and the RMP.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

4.3.3. Tivicay - dolutegravir - EMEA/H/C/002753/X/0058/G

ViiV Healthcare B.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Martin Huber

Scope: "- Extension application to add a new pharmaceutical form associated with new strength (5 mg dispersible tablet). The new presentation is indicated for the treatment of HIV infected children from 4 weeks of life and weighing at least 3 kilograms.
- Type II variation (C.I.4) to update the currently approved Product Information, Labelling and Package Leaflet for the existing film-coated tablets (10 mg, 25 mg and 50 mg) for children 6 years and older and weighing at least 15 kg. The application comprises PK, safety, and efficacy data from the Phase I/II study (P1093) and PK and safety data from relevant sub-studies nested within the Phase II/III Study ODYSSEY (PENTA 20).
In addition, the applicant took the opportunity to amend section 4.1 of the SmPC, the indication for the approved Tivicay film-coated tablets to clarify that children should be "aged at least 6 years" as the current approved indication is inclusive of those aged 6 years.
The RMP (version 16) is updated in accordance."

Action: For adoption

The Committee discussed the issues identified in this application, concerning some quality and clinical issues and the RMP.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

4.4. Update on on-going extension application according to Annex I of Commission Regulation (EC) No 1234/2008

No items

4.5. Re-examination procedure of extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008

No items

5. Type II variations - variation of therapeutic indication procedure according to Annex I of Commission Regulation (EC) No 1234/2008

5.1. Type II variations - variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008; Opinions or Requests for supplementary information

5.1.1. Brilique - ticagrelor - EMEA/H/C/001241/II/0047/G

AstraZeneca AB

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Menno van der Elst

Scope: "Extension of indication to include, in co-administration with acetylsalicylic acid (ASA), the prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) and type 2 diabetes mellitus (T2DM) without a history of myocardial infarction who have undergone percutaneous coronary intervention (PCI) based on the final results of study D513BC00001 (THEMIS), a phase III multinational, randomised, double-blind, placebo controlled study to evaluate the effect of ticagrelor twice daily on the incidence of cardiovascular death, myocardial infarction or stroke in patients with T2DM; as a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated.
Update of section 4.8 of the SmPC regarding new safety information on traumatic haemorrhages based on the final results from study D513BC00001 (THEMIS) and data from the ticagrelor clinical development programme and post-marketing data. The Package Leaflet is updated in accordance. The RMP version 12 has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 14.11.2019.

The Committee discussed the issues identified in this application, mainly concerning the appropriate target population.

The Committee adopted a 2nd request for supplementary information with a specific timetable.

5.1.2. Cosentyx - secukinumab - EMEA/H/C/003729/II/0057

Novartis Europharm Limited

Rapporteur: Tuomo Lapveteläinen, PRAC Rapporteur: Eva A. Segovia

Scope: "Extension of indication to include the treatment of moderate to severe plaque psoriasis in children and adolescents from the age of 6 years, who are candidates for

systemic therapy for Cosentyx; as a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. Section 6.6 of the SmPC for the solution for injection is also updated. The Package Leaflet is updated in accordance. In addition, the marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. The RMP version 6.0 has also been submitted. Furthermore, the Annex II is brought in line with the latest QRD template version 11.0."

Action: For adoption

Request for Supplementary Information adopted on 27.02.2020.

The Committee discussed the issues identified in this application, mainly concerning the benefit/risk in paediatric patients with a body weight less than 25 kg.

The Committee adopted a 2nd request for supplementary information with a specific timetable.

5.1.3. Doptelet - avatrombopag - EMEA/H/C/004722/II/0004/G

Dova Pharmaceuticals Ireland Limited

Rapporteur: Sinan B. Sarac, Co-Rapporteur: Andrea Laslop, PRAC Rapporteur: Eva A. Segovia

Scope: "Extension of indication to include the treatment of chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments; consequently, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. Additionally, the SmPC section 5.3 is updated with data from juvenile toxicity studies. Furthermore, an additional pack size has been introduced with subsequent updates of sections 6.5 and 8 of the SmPC. The Package Leaflet and Labelling are updated in accordance. Version 2.1 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.1."

Action: For adoption

The Committee discussed the issues identified in this application, mainly concerning the wording of the indication and the posology as well as some clarification on the clinical trial set up.

The Committee adopted a request for supplementary information with a specific timetable.

5.1.4. HyQvia - human normal immunoglobulin - EMEA/H/C/002491/II/0056

Baxalta Innovations GmbH

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Andrea Laslop, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of indication to replace the therapeutic indications of replacement therapy in hypogammaglobulinaemia and recurrent bacterial infections in patients with chronic lymphocytic leukaemia and multiple myeloma and hypogammaglobulinaemia in patients with HSCT, by the therapeutic indication of replacement therapy in secondary immunodeficiencies (SID) in patients who suffer from severe or recurrent infections, ineffective antimicrobial treatment and either proven specific antibody failure (PSAF) or serum IgG level of <4 g/l. for HyQvia; as a consequence, sections 4.1 and 4.2 of the SmPC

are updated. The Package Leaflet is updated in accordance. Version 10.0 of the RMP has also been submitted."

Action: For adoption

The Committee discussed the issues identified in this application, concerning some SmPC wording and the RMP.

The Committee adopted a request for supplementary information with a specific timetable.

5.1.5. Imfinzi - durvalumab - EMEA/H/C/004771/II/0014/G

AstraZeneca AB

Rapporteur: Sinan B. Sarac, Co-Rapporteur: Jorge Camarero Jiménez, PRAC Rapporteur: David Olsen

Scope: "Extension of indication to include the use of Imfinzi in combination with etoposide and either carboplatin or cisplatin for the first-line treatment of adults with extensive-stage small cell lung cancer (ES-SCLC). The proposed indication is supported by study D419QC00001 (CASPIAN), an ongoing Phase III randomised, multicentre, open-label, comparative study designed to determine the efficacy and safety of durvalumab, or durvalumab and tremelimumab, in combination with etoposide and platinum-based chemotherapy (EP) for the first-line treatment of patients with ES-SCLC.
In addition, the marketing authorisation holder (MAH) proposes to update sections 4.4 and 4.8 of the SmPC to update the safety information based on the Durvalumab Pan-Tumour Pool, a safety dataset comprising of 9 clinical studies building on the existing safety database and summarising the safety information for durvalumab monotherapy characterised across tumour types in the durvalumab clinical program to date. The Package Leaflet is updated in accordance. The RMP version 2.1 has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 27.02.2020.

The Committee discussed the issues identified in this application, concerning some clinical efficacy and safety aspects.

The Committee adopted a 2nd request for supplementary information with a specific timetable.

5.1.6. Invokana - canagliflozin - EMEA/H/C/002649/II/0046

Janssen-Cilag International NV

Rapporteur: Martina Weise, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Martin Huber

Scope: "Update of sections 4.1 , 4.2, , 4.4, 4.8, 5.1 and 6.6 of the Summary of Product Characteristics to modify the therapeutic indication for Invokana (canagliflozin) based upon new clinical efficacy and safety data from the Phase 3 study: Canagliflozin and Renal Events in Diabetes with Established Nephropathy Clinical Evaluation Trial (CREDENCE) (DNE3001). This study provides data on the use of Invokana in addition to standard of care in diabetic kidney disease patients. The Package Leaflet is updated accordingly. The RMP version 8.5 has also been agreed. In addition, the list of local representatives in the Package Leaflet has

been revised. The variation leads to amendments to the Summary of Product Characteristics and Package Leaflet and to the Risk Management Plan (RMP)."

Possible oral explanation

Action: For adoption

Request for Supplementary Information adopted on 30.04.2020, 27.02.2020, 14.11.2019.

See 2.3

The CHMP agreed that no oral explanation is needed at this time.

The members were informed that the applicant withdrew the request for an additional 1-year marketing protection.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

5.1.7. Kyprolis - carfilzomib - Orphan - EMEA/H/C/003790/II/0045

Amgen Europe B.V.

Rapporteur: Jorge Camarero Jiménez, Co-Rapporteur: Alexandre Moreau

Scope: "Extension of existing indication to include combination of Kyprolis with daratumumab and dexamethasone; as a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance."

Action: For adoption

The Committee discussed the issues identified in this application, concerning some clinical efficacy and safety aspects.

The Committee adopted a request for supplementary information with a specific timetable.

5.1.8. Lynparza - olaparib - EMEA/H/C/003726/II/0033

AstraZeneca AB

Rapporteur: Alexandre Moreau, Co-Rapporteur: Koenraad Norga, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension of indication to support the use of Lynparza tablets (100 mg and 150 mg) for the maintenance treatment of gBRCAm metastatic pancreatic cancer based on the results from the pivotal Phase 3 study, POLO; as a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the marketing authorisation holder (MAH) took the opportunity to update section 4.8 for Lynparza hard capsules (50 mg) to revise the list of ADR based on the pooled safety data analysis. The RMP version 18 has also been submitted. Furthermore, the PI is brought in line with the latest guideline regarding the sodium content. The MAH also took the occasion

to include some minor editorial changes in the PI."

Possible oral explanation

Action: For adoption

Request for Supplementary Information adopted on 30.04.2020, 30.01.2020, 17.10.2019.

See 2.3

An oral explanation was held on Monday, 25 May 2020. The presentation by the applicant focused on the clinical efficacy data in support of the application.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by majority (26 out of 30 votes) together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The divergent position (Alexandre Moreau, Simona Stankeviciute, Johann Lodewijk Hillege, Martina Weise) was appended to the opinion.

The summary of opinion was circulated for information.

5.1.9. Ofev - nintedanib - EMEA/H/C/003821/II/0027

Boehringer Ingelheim International GmbH

Rapporteur: Peter Kiely, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Nikica Mirošević Skvrce

Scope: "Extension of indication to include new indication for OFEV for the treatment of other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype based on the results of pharmacology studies and the double-blind, randomised, placebo-controlled phase III trial (INBUILD). Consequently, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated in order to reflect the use of Ofev in the new indication. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor formatting changes in the PI. Furthermore, the PI is brought in line with the latest QRD template version 10.1. The RMP version 9.1 has also been adopted.
The variation leads to amendments to the Summary of Product Characteristics, Annex II and Package Leaflet and to the Risk Management Plan (RMP).", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 26.03.2020, 12.12.2019.

The CHMP was informed about the withdrawal of the orphan designation for Ofev as requested by the MAH.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP

recommendations.

The summary of opinion was circulated for information.

5.1.10. Olumiant - baricitinib - EMEA/H/C/004085/II/0016

Eli Lilly Nederland B.V.

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Bart Van der Schueren, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include a new indication in the treatment of moderate to severe atopic dermatitis in adult patients who are candidates for systemic therapy for Olumiant; as a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Minor editorial changes were brought to the labelling. Furthermore, the Annex II is brought in line with the latest QRD template version 10.1. The RMP version 8.1 has also been submitted.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 26.03.2020.

The Committee discussed the issues identified in this application, concerning some clinical safety aspects.

The Committee adopted a 2nd request for supplementary information with a specific timetable.

5.1.11. Orfadin - nitisinone - EMEA/H/C/000555/II/0071

Swedish Orphan Biovitrum International AB

Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension of indication to include treatment of adult patients with alkaptonuria (AKU) for Orfadin; as a consequence, sections 4.1, 4.2, 4.4, 4.6, 4.8, 5.1 and 10 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.2 of the RMP has also been submitted accordingly and includes an update in accordance with GVP Module V Revision 2.", Request for 1 year of data exclusivity for a new indication (Article 10(5) of Directive 2001/83/EC)

Action: For adoption

The Committee discussed the issues identified in this application, mainly concerning the clinical efficacy in the sought indication.

The Committee adopted a request for supplementary information with a specific timetable.

5.1.12. Saxenda - liraglutide - EMEA/H/C/003780/II/0026

Novo Nordisk A/S

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Mark Ainsworth, PRAC Rapporteur:

Menno van der Elst

Scope: "Extension of indication to include treatment as an adjunct to a healthy nutrition and physical activity counselling for weight management in adolescent patients from the age of 12 years and above with body weight above 60 kg and obesity (BMI corresponding to ≥30 kg/m2 for adults), based on Study NN8022-4180 that evaluated the efficacy of liraglutide 3.0 mg in adolescents aged 12 to less than 18 years with obesity. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are being updated and the Package Leaflet is updated in accordance. The application relates to paediatric studies submitted according to Article 46 of the paediatric regulation. The application included an updated RMP version 32.0."

Action: For adoption

The Committee discussed the issues identified in this application, mainly relating to some clinical safety and efficacy aspects, including the appropriate target population.

The Committee adopted a request for supplementary information with a specific timetable.

5.1.13. Sivextro - tedizolid phosphate - EMEA/H/C/002846/II/0035

Merck Sharp & Dohme B.V.

Rapporteur: Bruno Sepodes, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension of indication (treatment of ABSSSI in adults) to include adolescent population from 12 years old and older for Sivextro; as a consequence, sections 4.1, 4.2, 4.8 and 5.2 of the SmPC are updated. Sections 1 and 2 of the Package Leaflet are updated in accordance. The updated RMP version 5.1 has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to bring the PI in line with the latest QRD template version 10.1"

Action: For adoption

Request for Supplementary Information adopted on 27.02.2020.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

5.1.14. Taltz - ixekizumab - EMEA/H/C/003943/II/0031

Eli Lilly Nederland B.V.

Rapporteur: Kristina Dunder, Co-Rapporteur: Peter Kiely, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of indication to include the treatment of moderate to severe plaque psoriasis in children from the age of 6 years and adolescents who are candidates for systemic therapy for Taltz; as a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the

SmPC are updated with new safety and efficacy information. The Package Leaflet is updated in accordance. In addition, the marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. The RMP version 7.1 has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 30.04.2020, 30.01.2020.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

5.1.15. Tecentriq - atezolizumab - EMEA/H/C/004143/II/0039

Roche Registration GmbH

Rapporteur: Sinan B. Sarac, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva

Scope: "Extension of indication to include, in combination with bevacizumab, the treatment of patients with unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy, based on the results of the pivotal study YO40245 (IMbrave150) as well as data from Arms A and F of the supportive Phase Ib study GO30140. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the Tecentriq 1200 mg concentrate for solution for infusion SmPC are updated. The Package Leaflet is updated in accordance. An updated RMP version 13.0 was provided as part of the application."

Action: For adoption

The Committee discussed the issues identified in this application, mainly concerning some clinical efficacy aspects including the appropriate target population.

The Committee adopted a request for supplementary information with a specific timetable.

5.1.16. Trumenba - meningococcal group B vaccine (recombinant, adsorbed) - EMEA/H/C/004051/II/0013

Pfizer Europe MA EEIG

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Jean-Michel Dogné

Scope: "Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC based on the results from two paediatric studies: B1971017 and B1971035. The MAH took the opportunity to carry out typographical and linguistic improvements throughout the PI. The Package Leaflet is updated in accordance. The RMP version 2.0 has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to submit a corrected version of the final report of study B1971016, which was included in the initial marketing authorisation application."

Action: For adoption

Request for Supplementary Information adopted on 26.03.2020, 14.11.2019, 25.07.2019, 28.02.2019.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

5.1.17. Vokanamet - canagliflozin / metformin - EMEA/H/C/002656/II/0051

Janssen-Cilag International NV

Rapporteur: Martina Weise, PRAC Rapporteur: Menno van der Elst

Scope: "Update of sections 4.4, 4.8, 5.1 and 6.6 of the Summary of Product Characteristics based upon new safety data from the Phase 3 study: Canagliflozin and Renal Events in Diabetes with Established Nephropathy Clinical Evaluation Trial (CREDENCE) (DNE3001). Furthermore, minor editorial changes in other sections of the SmPC. The Package Leaflet is updated accordingly. The RMP version 8.5 has also been agreed. In addition, the list of local representatives in the Package Leaflet has been revised."

Action: For adoption

Request for Supplementary Information adopted on 30.04.2020, 27.02.2020, 14.11.2019.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

5.1.18. Xtandi - enzalutamide - EMEA/H/C/002639/II/0047/G

Astellas Pharma Europe B.V.

Rapporteur: Jorge Camarero Jiménez, PRAC Rapporteur: Eva A. Segovia

Scope: "C.1.6: Extension of indication to include the treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) for Xtandi in combination with androgen deprivation therapy; As a consequence, sections 4.1, 4.7, 4.8, 5.1, 5.3 and 6.6 of the SmPC are updated. Furthermore, the MAH took the opportunity to make corrections to section 4.7. The Package Leaflet is updated in accordance. The RMP version 13.0 has also been submitted.
C.1.4: Update of section 5.1 of the SmPC based the 5-year Overall Survival (OS) results obtained from the PREVAIL study (MDV310003), a phase 3 study of enzalutamide in chemotherapy naïve patients with metastatic prostate cancer that progressed on ADT."

Oral explanation

Action: For adoption

Request for Supplementary Information adopted on 17.10.2019.

See 2.3

An oral explanation was held on Tuesday, 26 May 2020. The presentation by the applicant focused on some aspects concerning the clinical study conduct.

The Committee adopted a 2nd request for supplementary information with a specific timetable.

5.1.19. Xyrem - sodium oxybate - EMEA/H/C/000593/II/0076

UCB Pharma S.A.

Rapporteur: Bruno Sepodes, Co-Rapporteur: Mark Ainsworth, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Extension of indication to include adolescents and children older than 7 years for Xyrem; As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. The updated version (9.0) of the RMP was submitted."

Action: For adoption

Request for Supplementary Information adopted on 12.12.2019, 29.05.2019, 15.11.2018.

The Committee discussed the issues identified in this application, concerning some SmPC wording and the feasibility of a PASS study.

The Committee adopted a 4th request for supplementary information with a specific timetable.

5.1.20. Zejula - niraparib - Orphan - EMEA/H/C/004249/II/0019

GlaxoSmithKline (Ireland) Limited

Rapporteur: Bjorg Bolstad, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Jan Neuhauser

Scope: "Extension of indication to include the maintenance treatment of adult patients with advanced high-grade ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy for Zejula in monotherapy; as a consequence, sections 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The MAH is also taking the opportunity to make minor corrections throughout the PI. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted to add the new indication, bring it in line with the RMP template Rev. 2.0.1 and update due dates for category 3 studies.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

The Committee discussed the issues identified in this application, mainly relating to the indication wording as well as the request for 1 year of market protection.

The Committee adopted a request for supplementary information with a specific timetable.

5.2. Update on on-going Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

5.2.1. Fycompa - perampanel - EMEA/H/C/002434/II/0047

Eisai GmbH

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Adrien Inoubli

Scope: "Extension of indication to include adjunctive treatment in paediatric patients from 2 to 11 years of age in Partial-Onset (focal) Seizures with or without secondary generalisation and Primary Generalised Tonic-Clonic Seizures with idiopathic generalised epilepsy for Fycompa. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. The RMP version 4.3 has also been submitted.",

Letter from the applicant dated 19 May 2020 requesting an extension of clock-stop to respond to the request for supplementary information adopted in April 2020.

Action: For adoption

Request for Supplementary Information adopted on 30.04.2020, 12.12.2019.

The CHMP agreed to the request by the applicant for an extension of clock-stop to respond to the request for supplementary information adopted in April 2020.

5.3. Re-examination of Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

No items

6. Ancillary medicinal substances in medical devices

6.1. Ancillary medicinal substances in medical devices; Opinions/ Day 180 list of outstanding issues / Day 120 list of questions

No items

6.2. Update of Ancillary medicinal substances in medical devices

No items

7. Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use)

7.1. Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use)

7.1.1. IV Zanamivir - zanamivir- EMEA/H/K/002288

GlaxoSmithKline Research & Development Limited; treatment of pandemic A(H1N1)v infection or infection due to seasonal influenza A or B virus.

Compassionate Use Rapporteur: Kristina Dunder, Compassionate Use Co-Rapporteur: Alexandre Moreau

Scope: Termination of the compassionate use programme as of 06 May 2019

Action: For information

The CHMP noted the termination of the compassionate use programme.

8. Pre-submission issues

8.1. Pre-submission issue

8.1.1. dengue virus serotype 1* (live, attenuated); *genes of serotype-specific surface proteins engineered into dengue type 2 backbone, dengue virus serotype 2 (live, attenuated),dengue virus serotype 3* (live, attenuated); *genes of serotype-specific surface proteins engineered into dengue type 2 backbone, dengue virus serotype 4* (live, attenuated); *genes of serotype-specific surface proteins engineered into dengue type 2 backbone - H0005362

Active immunisation for the prevention of dengue disease caused by any serotype in individuals 2 to 60 years of age.

Scope: Briefing note and the Rapporteurs' recommendation on the request for accelerated assessment

Action: For adoption

The CHMP agreed to the request for accelerated assessment and adopted the briefing note and Rapporteurs' recommendation on the Request for Accelerated Assessment.

8.1.2. risdiplam - H0005145

Treatment of Spinal Muscular Atrophy (therapeutic area – neurology).

Scope: Briefing note and the Rapporteurs' recommendation on the request for accelerated assessment

Action: For adoption

The CHMP agreed to the request for accelerated assessment and adopted the briefing note and Rapporteurs' recommendation on the Request for Accelerated Assessment.

8.2. Priority Medicines (PRIME)

Disclosure of information related to priority medicines cannot be released at present time as these contain commercially confidential information

8.2.1. List of applications received

Action: For information

The CHMP noted the information

8.2.2. Recommendation for PRIME eligibility

Action: For adoption

The CHMP adopted the recommendation for PRIME eligibility. The CHMP reviewed 2 recommendations for eligibility to PRIME: All were denied.

The individual outcomes are listed in PRIME Monthly Report on EMA website.

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Bavencio - avelumab - EMEA/H/C/004338/II/0013

Merck Europe B.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Hans Christian Siersted

Scope: "Update of section 5.1 of the SmPC in order to update efficacy information following results from study EMR100070-003 Part B listed as a specific obligation in the Annex II; this is a Phase II, open-label, multicenter trial to investigate the clinical activity and safety of avelumab (MSB0010718C) in subjects with Merkel cell carcinoma. With this submission the company is also taking the opportunity to update annex-II proposing deletion of the specific obligation and proposing the switch from conditional to full marketing authorisation. The package leaflet and the RMP (version 2.1) are updated accordingly."

Action: For adoption

Request for Supplementary Information adopted on 27.02.2020.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP

recommendations.

9.1.2. Fabrazyme - agalsidase beta - EMEA/H/C/000370/II/0116

Genzyme Europe BV

Rapporteur: Johann Lodewijk Hillege

Scope: "Update of sections 4.2 and 5.1 of the SmPC in order to change posology recommendations in adults, children and adolescents aged 8 years and older by removing the information on the lower dosing regimens that have been used in clinical studies and update the clinical information based on the review of published scientific literature including 3 observational studies in patients remaining on standard dose of Fabrazyme or switching to low-dose Fabrazyme (0.5 mg/kg every 2 weeks) or to the registered dose of agalsidase alfa (0.2 mg/kg every 2 weeks). In addition, the marketing authorisation holder (MAH) took the opportunity to propose changes in the Product Information according to the QRD templates and current guidelines, including new warnings related to sodium excipient and traceability of biological medicinal products."

Action: For adoption

The Committee discussed the issues identified in this application, mainly concerning the wording of section 5.1 of the SmPC.

The Committee adopted a request for supplementary information with a specific timetable.

9.1.3. Prevymis - letermovir - EMEA/H/C/004536/II/0016/G, Orphan

Merck Sharp & Dohme B.V.

Rapporteur: Filip Josephson

Scope: "C.I.4 (type II) – Update of sections 4.2, 4.4, 6.2 and 6.6 of the SmPC to include the requirement to use an in-line filter at the point of administration, and avoid the use of the medicinal product with IV bags and infusion set materials containing polyurethane or the plasticizer diethylhexyl phthalate (DEHP), for finished product Prevymis 240 mg and 480 mg concentrate for solution for infusion (EU/1/17/1245/003-004). The package leaflet and labelling are updated accordingly.

B.II.d.1.z (type IB).

C.1.11.z (type IB) - Change in the due date of the Annex II condition for the medicinal product Prevymis 240 mg and 480 mg concentrate for solution for infusion (EU/1/17/1245/003-004).

The MAH took the opportunity to relocate the information regarding to sodium content in the Prevymis 240 mg/ 480 mg film-coated tablets (EU/1/17/1245/001-002) from section 2 to section 4.4 of the SmPC and to slightly update the description of the packaging from section 6.5 of the SmPC."

Action: For discussion

Request for Supplementary Information adopted on 26.03.2020, 12.12.2019.

The CHMP discussed the issues identified in this application.

The Committee confirmed that all issues previously identified in this application had been

addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The CHMP noted the DHPC and communication plan.

9.1.4. Tecfidera - dimethyl fumarate - EMEA/H/C/002601/II/0063

Biogen Netherlands B.V.

Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber

Scope: "Update of sections 4.4 and 4.8 of the SmPC to reflect PML in the setting of mild lymphopenia based on data submitted in the ongoing PSUSA/00010143/201903. The Package Leaflet is updated accordingly. Additionally, the Product Information has been updated in line with QRD template (version 10.1).",

PRAC advice

Action: For discussion

Request for Supplementary Information adopted on 30.01.2020, 19.09.2019.

The CHMP noted the PRAC advice.

The Committee discussed the issues identified in this application, mainly concerning some safety measures as proposed by the PRAC.

The Committee adopted a 3rd request for supplementary information with a specific timetable.

9.1.5. Kolbam – cholic acid - EMEA/H/C/002081

Retrophin Europe Ltd

Rapporteur: Konstantinos Markopoulos, Co-Rapporteur: Peter Kiely, PRAC Rapporteur: Agni Kapou

Scope: Withdrawal of marketing authorisation

Action: For information

The CHMP noted the applicants' intention to withdraw their marketing authorisation.

10. Referral procedures

10.1. Procedure for Centrally Authorised products under Article 20 of Regulation (EC) No 726/2004

10.1.1. Yondelis - EMEA/H/C/0773/A-20/0060

MAH: Pharma Mar S.A.

Rapporteur: Sinan B. Sarac, Co-Rapporteur: Jorge Camarero Jiménez

Scope: List of outstanding issues

Action: For adoption

European Commission triggered a referral procedure under Article 20 of Regulation (EC) No 726/2004 to request CHMP to assess study OVC-3006, which failed to meet its endpoints in the indication of ovarian cancer, and its impact on the benefit risk balance for the centrally authorised medicinal product(s) Yondelis (trabectedin).

The CHMP adopted a list of questions with a specific timetable.

Submission of responses: 19.06.2020

Re-start of the procedure: 25.06.2020

Rapporteur/co-rapporteur assessment report(s) circulated to CHMP: 10.07.2020

Comments: 15.07.2020

Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP: 17.07.2020

CHMP list of outstanding issues or CHMP opinion: July 2020 CHMP

10.2. Requests for CHMP Opinion under Article 5(3) of Regulation (EC) No 726/2004

10.2.1. Presence of nitrosamine impurities in human medicinal products containing chemically synthesised active pharmaceutical ingredients EMEA/H/A-5(3)/1490

MAHs: various

Referral Rapporteur: Martina Weise, Referral Co-Rapporteurs: Kristina Dunder

Scope: Opinion

Action: For adoption

The CHMP discussed the outstanding issues and agreed to further update the assessment report and to postpone the opinion to June 2020 CHMP.

10.3. Procedure under Articles 5(2) and 10 of Regulation (EC) No 726/2004

No items

10.4. Disagreement between Member States on application for medicinal product (potential serious risk to public health) –under Article 29(4) of Directive 2001/83/EC

No items

10.5. Harmonisation - Referral procedure under Article 30 of Directive 2001/83/EC

No items

10.6. Community Interests - Referral under Article 31 of Directive 2001/83/EC

10.6.1. Panexcell Clinical Laboratories Priv. Ltd - Multiple NAPs (EMEA/H/A-31/1494)

MAH: various

Referral Rapporteur: Janet Koenig, Referral Co-Rapporteur: Jayne Crowe

Scope: List of outstanding issues

Action: For adoption

Article 31 procedure triggered by the German Federal Institute of Drugs and Medical Devices (BfArM) concerning the contract research organisation (CRO) Panexcell Clinical Laboratories Priv. Ltd. located in Navi Mumbai 400 701, India

The CHMP adopted a list of questions with a specific timetable.

Submission of responses: 19.06.2020

Re-start of the procedure: 25.06.2020

Rapporteur/co-rapporteur joint assessment report circulated to CHMP: 10.07.2020

CHMP comments: 15.07.2020

Updated rapporteur/co-rapporteur joint assessment report circulated to CHMP: 17.07.2020

Oral explanation / CHMP opinion: July 2020 CHMP

10.7. Re-examination Procedure under Article 32(4) of Directive 2001/83/EC

No items

10.8. Procedure under Article 107(2) of Directive 2001/83/EC

No items

10.9. Disagreement between Member States on Type II variation– Arbitration procedure initiated by MAH under Article 6(13) of Commission Regulation (EC) No 1084/2003

No items

10.10. Procedure under Article 29 of Regulation (EC) 1901/2006

No items

10.11. Referral under Article 13 Disagreement between Member States on Type II variation– Arbitration procedure initiated by Member State under Article 13 (EC) of Commission Regulation No 1234/2008

No items

11. Pharmacovigilance issue

11.1. Early Notification System

May 2020 Early Notification System on envisaged CHMP/CMDh outcome accompanied by communication to the general public.

Action: For information

12. Inspections

12.1. GMP inspections

Information related to GMP inspections will not be published as it undermines the purpose of such inspections

12.2. GCP inspections

Information related to GCP inspections will not be published as it undermines the purpose of such inspections

12.3. Pharmacovigilance inspections

Information related to Pharmacovigilance inspections will not be published as it undermines the purpose of such inspections

12.4. GLP inspections

Information related to GLP inspections will not be published as it undermines the purpose of such inspections

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

No items

13.2. Innovation Task Force briefing meetings

No items

13.3. Requests for CHMP Opinion under Article 57(1)J and (1)P of Regulation (EC) No 726/2004

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

No items

14.2. Coordination with EMA Scientific Committees

Note: Reports of EMA Scientific Committees are available in the MMD folder of the respective Committee.

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

Summary of recommendations and advice of PRAC meeting held on 11-14 May 2020

Action: For information

The CHMP noted the Summary of recommendations and advice.

List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for May 2020

Action: For adoption

The CHMP adopted the EURD list.

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at May 2020 PDCO

Action: For information

The CHMP noted the information.

14.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

14.3.1. Ad-hoc Influenza Working Group

Scope: Amended May 2020 - EU Strain selection for the Influenza Vaccines for the Season 2020/2021: Report from the Ad Hoc Influenza working group to the BWP adopted via written procedure on 08 May 2020.

Action: For information

The CHMP noted the information.

Scope: Amended May 2020 - EU Recommendation for the Seasonal Influenza Vaccine Composition for the Season 2020/2021 adopted via written procedure on 08 May 2020.

Action: For information

The CHMP noted the information.

14.3.2. Biologics Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

Reports from BWP May 2020 meeting to CHMP for adoption:

- 10 reports on products in scientific advice and protocol assistance
- 14 reports on products in pre-authorisation procedures
- 4 reports on products in plasma master file

Action: For adoption

The CHMP adopted the BWP reports.

14.3.3. Name Review Group (NRG)

Table of Decisions of the NRG meeting held on 23 April 2020.

Action: For adoption

The CHMP adopted the table of decision.

14.3.4. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel,

Report from the SAWP meeting held on 11–14 May 2020, Table of conclusions

Action: For information

The CHMP noted the report.

Call for interest for nomination of a replacement SAWP member and his/her alternate.

The required area of expertise is oncology and anti-infectives. The letters of candidacy together with the CV of both member and alternate, as per the SAWP Rules of Procedure, should be sent directly to the SAWP Secretariat

Action: for information

The CHMP noted the call for nomination.

Scientific advice letters: Disclosure of information related to scientific advice letters cannot be released at present time as these contain commercially confidential information.

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

14.6. Contacts of the CHMP with external parties and interaction with the Interested Parties to the Committee

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

No items

15. Any other business

15.1. AOB topic

15.1.1. Update on COVID-19

Action: For information

The CHMP noted the update.

16. List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the May 2020 CHMP meeting.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Harald Enzmann	Chair	Germany	No interests declared	
Andrea Laslop	Member	Austria	No interests declared	
Milena Stain	Alternate	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Bart Van der Schueren	Alternate	Belgium	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Emilia Mavrokordatou	Alternate	Cyprus	No interests declared	
Ondřej Slanař	Member	Czech Republic	No interests declared	
Tomas Radimersky	Alternate	Czech Republic	No interests declared	
Sinan B. Sarac	Member	Denmark	No interests declared	
Mark Ainsworth	Alternate	Denmark	No interests declared	
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
Tuomo Lapveteläinen	Alternate	Finland	No interests declared	
Alexandre Moreau	Member	France	No interests declared	
Martina Weise	Member	Germany	No restrictions applicable to this meeting	
Janet Koenig	Alternate	Germany	No interests declared	
Konstantinos Markopoulos	Member	Greece	No interests declared	
Eleftheria Nikolaidi	Alternate	Greece	No interests declared	
Melinda Sobor	Member	Hungary	Direct interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Agnes Gyurasics	Alternate	Hungary	No interests declared	
Hrefna Gudmundsdottir	Alternate	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Peter Kiely	Alternate	Ireland	No interests declared	
Daniela Melchiorri	Member	Italy	No restrictions applicable to this meeting	
Giuseppa Pistritto	Alternate	Italy	No interests declared	
Elita Poplavska	Alternate	Latvia	No interests declared	
Simona Stankeviciute	Alternate	Lithuania	No interests declared	
Martine Trauffler	Member	Luxembourg	No interests declared	
John Joseph Borg	Member	Malta	No interests declared	
Johann Lodewijk Hillege	Member	Netherlands	No interests declared	
Paula Boudewina van Hennik	Alternate	Netherlands	No interests declared	
Bjorg Bolstad	Member	Norway	No interests declared	
Ingrid Wang	Alternate	Norway	No interests declared	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
Bruno Sepodes	Member (Vice-Chair)	Portugal	No interests declared	
Fatima Ventura	Alternate	Portugal	No restrictions applicable to this meeting	
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Francisek Drafi	Member	Slovakia	No interests declared	
Dorota Distlerova	Alternate	Slovakia	No restrictions applicable to this meeting	
Nevenka Trsinar Brodt	Alternate	Slovenia	No interests declared	
Maria Concepcion Prieto Yerro	Member	Spain	No interests declared	
Jorge Camarero Jiménez	Alternate	Spain	No participation in final deliberations and voting on:	- risdiplam - H0005145, - entrectinib - EMEA/H/C/004936, - satralizumab - EMEA/H/C/004788,

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
				- pertuzumab / trastuzumab - EMEA/H/C/005386, Tecentriq - atezolizumab - EMEA/H/C/004143/II/0039
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Christian Gartner	Co-opted member	Austria	No restrictions applicable to this meeting	
Koenraad Norga	Co-opted member	Belgium	No participation in final deliberations and voting on:	Zejula - niraparib - EMEA/H/C/004249/II/0019; IV Zanamivir - zanamivir- EMEA/H/K/002288
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czech Republic	No interests declared	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Kerstin Wickstrom	Expert - via telephone*	Iceland	No restrictions applicable to this meeting	
Jeanette McCallion	Expert - via telephone*	Ireland	No interests declared	
Rosemary Kane Maher	Expert - via telephone*	Ireland	No restrictions applicable to this meeting	
Marc van der Valk	AHEG chair	Netherlands	No restrictions to give the AHEG report as AHEG chair	
Monique van Raamsdonk	Expert - via telephone*	Netherlands	No interests declared	
Aina Ovrebust	Expert - via telephone*	Norway	No interests declared	
Angelina Doriguzzi	Expert - via Adobe*	Austria	Indirect interests declared	
Susanne Urach	Expert - via Adobe*	Austria	No interests declared	
Olga Kholmanskikh	Expert - via Adobe*	Belgium	No interests declared	
Aaron Sosa	Expert - via Adobe*	Denmark	No restrictions applicable to this meeting	
Aldana Rosso	Expert - via Adobe*	Denmark	No interests declared	
Doris Hovgaard	Expert - via Adobe*	Denmark	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Ebru Gulsun Karakoc Madsen	Expert - via Adobe*	Denmark	No restrictions applicable to this meeting	
Elisabeth Penninga	Expert - via Adobe*	Denmark	No interests declared	
Kristine Moll Harboe	Expert - via Adobe*	Denmark	No interests declared	
Lene Hansen	Expert - via Adobe*	Denmark	No interests declared	
Mette Linnert Jensen	Expert - via Adobe*	Denmark	No interests declared	
Ole Weis Bjerrum	Expert - via Adobe*	Denmark	Indirect interests declared	
Johanna Lahteenvuo	Expert - via Adobe*	Finland	No interests declared	
Karri Penttila	Expert - via Adobe*	Finland	No interests declared	
Isabel Araujo Fernandez	Expert - via Adobe*	France	No restrictions applicable to this meeting	
Pierre Demolis	Expert - via Adobe*	France	No interests declared	
Andrea Dercks-Mueller	Expert - via Adobe*	Germany	No interests declared	
Anne Isabel Roth	Expert - via Adobe*	Germany	No interests declared	
Christiane Greiner	Expert - via Adobe*	Germany	No interests declared	
Christoph Unkrig	Expert - via Adobe*	Germany	No interests declared	
Elena Wolf	Expert - via Adobe*	Germany	No interests declared	
Joachim Ludwig	Expert - via Adobe*	Germany	No interests declared	
Jutta Dedorath	Expert - via Adobe*	Germany	No interests declared	
Martina Schuessler-Lenz	Expert - via Adobe*	Germany	No interests declared	
Ralph Meyer	Expert - via Adobe*	Germany	No interests declared	
Roland Froetschl	Expert - via Adobe*	Germany	No interests declared	
Fabrizio Galliccia	Expert - via Adobe*	Italy	No interests declared	
Berendina Maria van den Hoorn	Expert - via Adobe*	Netherlands	No interests declared	
Frank Holtkamp	Expert - via Adobe*	Netherlands	No interests declared	
Ingrid Evers van Gogh	Expert - via Adobe*	Netherlands	No restrictions applicable to this meeting	
Jaap Fransen	Expert - via Adobe*	Netherlands	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Jaap Goedemoed	Expert - via Adobe*	Netherlands	No interests declared	
Peter Mol	Expert - via Adobe*	Netherlands	No interests declared	
Anja Schiel	Expert - via Adobe*	Norway	No interests declared	
Agustin Portela	Expert - via Adobe*	Spain	No interests declared	
Ernesto Vera Sanchez	Expert - via Adobe*	Spain	No interests declared	
Meeting run with the help of EMA staff				

*Experts were only evaluated against the product(s) they have been invited to talk about.

17. Explanatory notes

The notes below give a brief explanation of the main sections and headings in the CHMP agenda and should be read in conjunction with the agenda or the minutes.

Oral explanations *(section 2)*

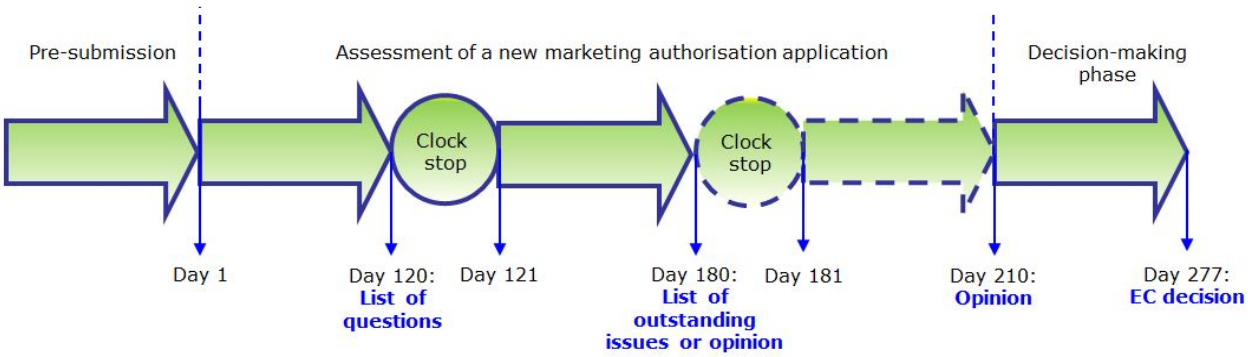
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures (section 10) but can relate to any other issue for which the CHMP would like to discuss with company representatives in person.

Initial applications *(section 3)*

This section lists applications for marketing authorisations of new medicines that are to be discussed by the Committee.

Section 3.1 is for medicinal products nearing the end of the evaluation and for which the CHMP is expected to adopt an **opinion** at this meeting on whether marketing authorisation should be granted. Once adopted, the CHMP opinion will be forwarded to the European Commission for a final legally binding decision valid throughout the EU.

The other items in the section are listed depending on the stage of the evaluation, which is shown graphically below:



The assessment of an application for a new medicine takes up to 210 'active' days. This active evaluation time is interrupted by at least one 'clock-stop' during which time the applicant prepares the answers to questions from the CHMP. The clock stop happens after day 120 and may also happen after day 180, when the CHMP has adopted a list of questions or outstanding issues to be addressed by the company. Related discussions are listed in the agenda under sections 3.2 (**Day 180 List of outstanding issues**) and 3.3 (**Day 120 list of questions**).

CHMP discussions may also occur at any other stage of the evaluation, and these are listed under section 3.4, **update on ongoing new applications for centralised procedures**.

The assessment leads to an opinion from the CHMP by day 210. Following a CHMP opinion the European Commission takes usually 67 days to issue a legally binding decision (i.e. by day 277 of the procedure). CHMP discussions on products that have received a CHMP opinion and are awaiting a decision are listed under section 3.6, **products in the decision making phase**.

Extension of marketing authorisations according to Annex I of Reg. 1234/2008 *(section 4)*

Extensions of marketing authorisations are applications for the change or addition of new strengths, formulations or routes of administration to existing marketing authorisations. Extension applications

follow a 210-day evaluation process, similarly to applications for new medicines (see figure above).

Type II variations - Extension of indication procedures *(section 5)*

Type II variations are applications for a change to the marketing authorisation which requires an update of the product information and which is not covered in section 4. Type II variations include applications for a new use of the medicine (extension of indication), for which the assessment takes up to 90 days. For the applications listed in this section, the CHMP may adopt an opinion or request supplementary information from the applicant.

Ancillary medicinal substances in medical devices *(section 6)*

Although the EMA does not regulate medical devices it can be asked by the relevant authorities (the so-called Notified Bodies) that are responsible for regulating these devices to give a scientific opinion on a medicinal substance contained in a medical device.

Re-examination procedures (new applications) under article 9(2) of regulation no 726/2004 *(section 3.5)*

This section lists applications for new marketing authorisation for which the applicant has requested a re-examination of the opinion previously issued by the CHMP.

Re-examination procedures *(section5.3)*

This section lists applications for type II variations (including extension of indication applications) for which the applicant has requested re-examination of the opinion previously issued by the CHMP.

Withdrawal of application *(section 3.7)*

Applicants may decide to withdraw applications at any stage during the assessment and a CHMP opinion will therefore not be issued. Withdrawals are included in the agenda for information or discussion, as necessary.

Procedure under article 83(1) of regulation (EC) 726/2004 (compassionate use) *(section 7)*

Compassionate use is a way of making available to patients with an unmet medical need a promising medicine which has not yet been authorised (licensed) for their condition. Upon request, the CHMP provides recommendations to all EU Member States on how to administer, distribute and use certain medicines for compassionate use.

Pre-submission issues *(section 8)*

In some cases the CHMP may discuss a medicine before a formal application for marketing authorisation is submitted. These cases generally refer to requests for an accelerated assessment for medicines that are of major interest for public health or can be considered a therapeutic innovation. In case of an accelerated assessment the assessment timetable is reduced from 210 to 150 days.

Post-authorisation issues *(section 9)*

This section lists other issues concerning authorised medicines that are not covered elsewhere in the agenda. Issues include supply shortages, quality defects, some annual reassessments or renewals or type II variations to marketing authorisations that would require specific discussion at the plenary.

Referral procedures *(section 10)*

This section lists referrals that are ongoing or due to be started at the plenary meeting. A referral is a procedure used to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines. In a referral, the EMA is requested to conduct a scientific assessment of a particular medicine or class of medicines on behalf of the EU. Further information on such procedures

can be found here.

Pharmacovigilance issues *(section 11)*

This section lists issues that have been discussed at the previous meeting of the PRAC, the EMA's committee responsible for evaluating and monitoring safety issues for medicines. Feedback is provided by the PRAC. This section also refers to the early notification system, a system used to notify the European regulatory network on proposed EMA communication on safety of medicines.

Inspections Issues *(section 12)*

This section lists inspections that are undertaken for some medicinal products. Inspections are carried out by regulatory agencies to ensure that marketing authorisation holders comply with their obligations. Inspection can relate to good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP) or good pharmacovigilance practice (GVP).

Innovation task force *(section 13)*

The Innovation Task Force (ITF) is a body set up to encourage early dialogue with applicants developing innovative medicines. Minutes from the last ITF meeting as well as any related issue that requires discussion with the CHMP are listed in this section of the agenda. Further information on the ITF can be found here.

Scientific advice working party (SAWP) *(section 14.3.1)*

This section refers to the monthly report from the CHMP's Scientific Advice Working Party (SAWP) on scientific advice given to companies during the development of medicines. Further general information on SAWP can be found here.

Satellite groups / other committees *(section 14.2)*

This section refers to the reports from groups and committees making decisions relating to human medicines: the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), the Committee for Orphan Medicinal Products (COMP), the Committee for Herbal Medicinal Products (HMPC), Paediatric Committee (PDCO), the Committee for Advanced Therapies (CAT) and the Pharmamacovigilance Risk Assessment Committee (PRAC).

Invented name issues *(section 14.3)*

This section list issues related to invented names proposed by applicants for new medicines. The CHMP has established the Name Review Group (NRG) to perform reviews of the invented names. The group's main role is to consider whether the proposed names could create a public-health concern or potential safety risk. Further information can be found here.

More detailed information on the above terms can be found on the EMA website: www.ema.europa.eu/

17 August 2020
EMA/CHMP/368067/2020

Annex to 25-28 May 2020 CHMP Minutes

Pre-submission and post-authorisations issues

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A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for May 2020: **For adoption**	Adopted.

A.2. Appointment of Rapporteur / Co-Rapporteur Full Applications

Final Outcome of Rapporteurship allocation for May 2020: **For adoption**	Adopted.

A.3. PRE-SUBMISSION ISSUES FOR INFORMATION

Information related to pre-submission of initial applications cannot be released at the present time as these contain commercially confidential information.

B. POST-AUTHORISATION PROCEDURES OUTCOMES

B.1. Annual re-assessment outcomes

B.1.1. Annual reassessment for products authorised under exceptional circumstances

Orphacol - cholic acid - EMEA/H/C/001250/S/0033, Orphan Laboratoires CTRS, Rapporteur: Konstantinos Markopoulos, PRAC Rapporteur: Sofia Trantza Request for Supplementary Information adopted on 30.04.2020, 27.02.2020.	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The Marketing Authorisation remains under exceptional circumstances. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP opinion.

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

B.2.1. Renewals of Marketing Authorisations requiring 2nd Renewal

Nucala - mepolizumab - EMEA/H/C/003860/R/0031 GlaxoSmithKline Trading Services Limited, Rapporteur: Peter Kiely, Co-Rapporteur: Ondřej Slanař, PRAC Rapporteur: Brigitte Keller-Stanislawski Request for Supplementary Information adopted on 30.04.2020.	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that an additional five-year renewal was required. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
Omidria - phenylephrine / ketorolac - EMEA/H/C/003702/R/0015 Omeros Ireland Limited, Rapporteur: Jayne	Positive Opinion adopted by consensus together with the CHMP assessment report and

Crowe, Co-Rapporteur: Agnes Gyurasics, PRAC Rapporteur: Jan Neuhauser Request for Supplementary Information adopted on 30.04.2020.	translation timetable. Based on the review of the available information, the CHMP was of the opinion that an additional five-year renewal was required. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
Orkambi - lumacaftor / ivacaftor - EMEA/H/C/003954/R/0056 Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Daniela Melchiorri, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald Request for Supplementary Information adopted on 28.05.2020.	Request for supplementary information adopted with a specific timetable.
Raxone - idebenone - EMEA/H/C/003834/R/0020, Orphan Santhera Pharmaceuticals (Deutschland) GmbH, Rapporteur: John Joseph Borg, Co-Rapporteur: Andrea Laslop, PRAC Rapporteur: Amelia Cupelli Request for Supplementary Information adopted on 26.03.2020.	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that an additional five-year renewal was required. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Aripiprazole Accord - aripiprazole - EMEA/H/C/004021/R/0019 Accord Healthcare S.L.U., Generic, Generic of Abilify, Rapporteur: John Joseph Borg, PRAC Rapporteur: Ana Sofia Diniz Martins Request for Supplementary Information adopted on 28.05.2020.	Request for supplementary information adopted with a specific timetable.
Briviact - brivaracetam - EMEA/H/C/003898/R/0025 UCB Pharma S.A., Rapporteur: Filip Josephson, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Adam Przybylkowski Request for Supplementary Information adopted on 28.05.2020.	Request for supplementary information adopted with a specific timetable.
CIAMBRA - pemetrexed - EMEA/H/C/003788/R/0006 Menarini International Operations Luxembourg S.A., Generic, Generic of Alimta, Rapporteur: Natalja Karpova, PRAC Rapporteur: Adrien Inoubli	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity.

	The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
Cinacalcet Mylan - cinacalcet - EMEA/H/C/004014/R/0011 Mylan S.A.S, Generic, Generic of Mimpara, Rapporteur: Tomas Radimersky, PRAC Rapporteur: Ulla Wändel Liminga Request for Supplementary Information adopted on 28.05.2020.	Request for supplementary information adopted with a specific timetable.
Cresemba - isavuconazole - EMEA/H/C/002734/R/0027, Orphan Basilea Pharmaceutica Deutschland GmbH, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Adam Przybylkowski Request for Supplementary Information adopted on 26.03.2020.	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
Ebymect - dapagliflozin / metformin - EMEA/H/C/004162/R/0046 AstraZeneca AB, Rapporteur: Kristina Dunder, Co-Rapporteur: Agnes Gyurasics, PRAC Rapporteur: Menno van der Elst Request for Supplementary Information adopted on 28.05.2020.	Request for supplementary information adopted with a specific timetable.
Edistride - dapagliflozin - EMEA/H/C/004161/R/0038 AstraZeneca AB, Rapporteur: Kristina Dunder, Co-Rapporteur: Martina Weise, PRAC Rapporteur: Annika Folin Request for Supplementary Information adopted on 28.05.2020.	Request for supplementary information adopted with a specific timetable.
Genvoya - elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide - EMEA/H/C/004042/R/0069 Gilead Sciences Ireland UC, Rapporteur: Bruno Sepodes, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Ilaria Baldelli Request for Supplementary Information adopted on 28.05.2020.	Request for supplementary information adopted with a specific timetable.
Imlygic - talimogene laherparepvec - EMEA/H/C/002771/R/0039, ATMP Amgen Europe B.V., Rapporteur: Olli Tenhunen, Co-Rapporteur: Rune Kjeken, PRAC Rapporteur: Brigitte Keller-Stanislawski Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 20.05.2020.	
Obizur - susoctocog alfa - EMEA/H/C/002792/R/0033 Baxalta Innovations GmbH, Rapporteur: Andrea Laslop, Co-Rapporteur: Tuomo Lapveteläinen, PRAC Rapporteur: Brigitte Keller-Stanislawski Request for Supplementary Information adopted on 28.05.2020.	Request for supplementary information adopted with a specific timetable.
Praxbind - idarucizumab - EMEA/H/C/003986/R/0019 Boehringer Ingelheim International GmbH, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Mark Ainsworth, PRAC Rapporteur: Menno van der Elst	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
Votubia - everolimus - EMEA/H/C/002311/R/0065, Orphan Novartis Europharm Limited, Rapporteur: Janet Koenig, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Martin Huber Request for Supplementary Information adopted on 30.04.2020.	Positive Opinion adopted by consensus together with the CHMP assessment report and translaation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
VPRIV - velaglucerase alfa - EMEA/H/C/001249/R/0045, Orphan Shire Pharmaceuticals Ireland Limited, Rapporteur: Martina Weise, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Martin Huber Request for Supplementary Information adopted on 26.03.2020.	Positive Opinion adopted by consensus together with the CHMP assessment report and translaation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.

B.2.3. Renewals of Conditional Marketing Authorisations

Bavencio - avelumab - EMEA/H/C/004338/R/0017 Merck Europe B.V., Rapporteur: Filip Josephson, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Hans Christian Siersted	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the risk-benefit balance remains favourable and that all specific obligations have been fulfilled,

	therefore the CHMP recommended granting of a Marketing Authorisation not subject to specific obligations. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
Translarna - ataluren - EMEA/H/C/002720/R/0057, Orphan PTC Therapeutics International Limited, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Liana Gross-Martirosyan Request for Supplementary Information adopted on 30.04.2020.	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted. The Marketing Authorisation remains conditional. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
VITRAKVI - larotrectinib - EMEA/H/C/004919/R/0006 Bayer AG, Rapporteur: Filip Josephson, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Rugile Pilviniene Request for Supplementary Information adopted on 28.05.2020.	Request for supplementary information adopted with a specific timetable:

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection **PRAC recommendations on signals adopted at the PRAC meeting held on 11-14 May 2020:**	
Signal of erroneous assay results for levels of anti-factor Xa activity with use of andexanet alfa: ONDEXXYA - andexanet alfa Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Maria Concepcion Prieto Yerro PRAC recommendation on a DHPC **Action**: For adoption	Adopted.

Signal of diverticulitis: OLUMIANT – baricitinib Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Bart Van der Schueren PRAC recommendation on a variation **Action**: For adoption	Adopted.
Signal of drug-drug interaction with serotonergic drugs leading to serotonin syndrome: BUVIDAL, SIXMO, SUBOXONE, ZUBSOLV, CYMBALTA, DULOXETINE LILLY, DULOXETINE MYLAN, DULOXETINE ZENTIVA, XERISTAR, YENTREVE, SANCUSO, ALOXI, PALONOSETRON ACCORD, AKYNZEO - buprenorphine, buprenorphine, naloxone, Selective serotonin reuptake inhibitors (SSRIs), Tricyclic antidepressants (TCAs), Other psychiatric medicines, Serotonin receptor agonists, Antiemetics, Other serotonergic drugs Rapporteur: various, Co-Rapporteur: various PRAC recommendation on a variation **Action**: For adoption	Adopted.
Signal on new information on the known risk of breast cancer: DUAVIVE - hormone replacement therapy (HRT) Rapporteur: Martina Weise, Co-Rapporteur: Mark Ainsworth PRAC recommendation on a variation **Action**: For adoption	Adopted.
Post-authorisation safety studies **PRAC recommendations on PASS results adopted at the PRAC meeting held on 11-14 May 2020 PRAC:**	

ADCETRIS (CAP) - EMEA/H/C/PSR/S/0022 (brentuximab vedotin) Applicant: Takeda Pharma A/S PRAC Rapporteur: Menno van der Elst Scope: MAH's response to PSR/S/002 [results for study MA25101: an observational cohort study of the safety of brentuximab vedotin in the treatment of relapsed or refractory CD30+ Hodgkin lymphoma and relapsed or refractory systemic anaplastic large cell lymphoma (sALCL) evaluating the occurrence of serious adverse events (SAEs) and adverse events of special interest (AESIs) and identifying and describing potential risk factors for peripheral neuropathy] as per the request for supplementary information (RSI) adopted January 2020 PRAC recommendation to CHMP **Action**: For adoption	Adopted.
PSUR procedures **PRAC recommendation for variation of the terms of the MA adopted at the PRAC meeting held on 11-14 May 2020:**	
EMEA/H/C/PSUSA/00000939/201910 (deferasirox) CAPS: **EXJADE** (EMEA/H/C/000670) (deferasirox), Novartis Europharm Limited, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Adrien Inoubli, "Period Covered From: 01/11/2018 To: 31/10/2019"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of the SmPC section 4.4 to revise the information on factors contributing to hepatic failure, and recommendation on treatment discontinuation in case of the gastrointestinal ulceration or haemorrhage. Additionally, the section 4.8 has been updated to remove the reference to dispersible tablets and pre-existing liver cirrhosis. Furthermore, the PRAC agreed to terminate the expedited reporting of "Increase in hepatic enzymes >10x ULN, Serious rise in creatinine, Results of renal biopsies, Cataracts, Hearing loss, Gallstones'' which is reflected by the deletion of the commitment in Annex II. The Icelandic and the Norwegian CHMP members agree with the above-mentioned

	recommendation of the CHMP.
EMEA/H/C/PSUSA/00002014/201910 (methotrexate) CAPS: **Jylamvo** (EMEA/H/C/003756) (methotrexate), Therakind (Europe) Limited, Rapporteur: Bruno Sepodes **Nordimet** (EMEA/H/C/003983) (methotrexate), Nordic Group B.V., Rapporteur: Bruno Sepodes NAPS: **NAPs** – EU , "Period Covered From: 31/10/2018 To: 31/10/2019"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 and Article 107g(3) of Directive 2001/83/EC the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the medicinal products containing the above referred active substance, concerning the following change(s): Update of section 4.2 of the SmPC and section 3 of the PL to include a statement on training in the use of methotrexate suitable for parenteral self-administration. Update of section 4.5 of the SmPC to revise existing wording for the interaction of methotrexate with nitrous oxide for methotrexate-containing products without any indication in oncology or extra-uterine pregnancy. Update of section 4.8 of the SmPC and the PL to add the adverse reaction "skin exfoliation / dermatitis exfoliative" with a frequency "not known" for all methotrexate containing products. Update of section 4.8 of the SmPC and the PL to add or amend the adverse reaction "paraesthesia / hypoaesthesia" (and to delete "in the extremities" as applicable) with a frequency of "very rare" for low dose methotrexate-containing products. Update of section 4.8 of the SmPC and the PL to add the adverse reaction "oedema" with a frequency "not known" for low dose methotrexate-containing products. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
EMEA/H/C/PSUSA/00002321/201910 (pazopanib) CAPS: **Votrient** (EMEA/H/C/001141) (pazopanib), Novartis Europharm Limited, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Hans Christian Siersted, "Period Covered From: 19/10/2018 To: 18/10/2019"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of sections 4.4 and 4.8 of the SmPC to add a warning on the adverse reaction Tumour lysis syndrome with a frequency of not known. The Package leaflet is updated accordingly.

	The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
EMEA/H/C/PSUSA/00010118/201909 (midazolam (oromucosal solution, treatment of prolonged, acute, convulsive seizures)) CAPS: **BUCCOLAM** (EMEA/H/C/002267) (midazolam), Shire Services BVBA, Rapporteur: Johann Lodewijk Hillege NAPS: **NAP** - EU PRAC Rapporteur: Liana Gross-Martirosyan, "Period Covered From: 10/09/2016 To: 09/09/2019"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 and Article 107g(3) of Directive 2001/83/EC the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended together with the detailed explanation of the scientific grounds for the differences with the PRAC recommendation, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the medicinal products containing the above referred active substance(s), concerning the following change(s): Update of section 4.8 of the SmPC to add the adverse reaction angioedema with a frequency not known. The Package leaflet is updated accordingly. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
EMEA/H/C/PSUSA/00010318/201910 (nintedanib (oncology indications)) CAPS: **Vargatef** (EMEA/H/C/002569) (nintedanib), Boehringer Ingelheim International GmbH, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Agni Kapou, "Period Covered From: 15/10/2018 To: 15/10/2019"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.4 of the SmPC to amend a warning on sepsis. The Package leaflet is updated accordingly. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
EMEA/H/C/PSUSA/00010534/201910 (irinotecan (liposomal formulations)) CAPS: **Onivyde pegylated liposomal** (EMEA/H/C/004125) (irinotecan hydrochloride trihydrate), Les Laboratoires Servier, Rapporteur: Filip Josephson, PRAC Rapporteur: David Olsen, "Period Covered From: 23/04/2019 To: 22/10/2019"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.5 of the SmPC to add regorafenib to the list of examples of UGT1A1 inhibitors. The Package leaflet is updated accordingly. The MAH also took the occasion to

	align the PI to QRD version 10.1. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
EMEA/H/C/PSUSA/00010723/201910 (durvalumab) CAPS: **Imfinzi** (EMEA/H/C/004771) (durvalumab), AstraZeneca AB, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: David Olsen, "Period Covered From: 01/05/2019 To: 31/10/2019"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Sections 4.4 and 4.8 of the SmPC are updated to reflect that cases of meningitis, encephalitis and Guillain-Barre syndrome have been reported with durvalumab in ongoing and completed trials. The Package leaflet has been updated accordingly. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.

B.4. EPARs / WPARs

Fingolimod Accord - fingolimod - EMEA/H/C/005191 Accord Healthcare S.L.U., treatment of multiple sclerosis, Generic, Generic of Gilenya, Generic application (Article 10(1) of Directive No 2001/83/EC) **WPAR**	For information only. Comments can be sent to the PL in case necessary.
Erlotinib Accord - erlotinib - EMEA/H/C/005071 Accord Healthcare S.L.U., treatment of lung and pancreatic cancers, Generic, Generic of Tarceva, Generic application (Article 10(1) of Directive No 2001/83/EC) **WPAR**	For information only. Comments can be sent to the PL in case necessary.
Fingolimod Mylan - fingolimod - EMEA/H/C/005282 Mylan Ireland Limited, treatment of multiple sclerosis, Generic, Generic of Gilenya, Generic application (Article 10(1) of Directive No 2001/83/EC) **WPAR**	For information only. Comments can be sent to the PL in case necessary.

B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES

Scopes related to Chemistry, Manufacturing, and Controls cannot be released at the present time

as these contain commercially confidential information.

B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects

Adcetris - brentuximab vedotin - EMEA/H/C/002455/II/0075/G, Orphan Takeda Pharma A/S, Rapporteur: Paula Boudewina van Hennik Opinion adopted on 28.05.2020.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Afstyla - lonoctocog alfa - EMEA/H/C/004075/II/0029/G CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 19.03.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Emtricitabine/Tenofovir disoproxil Zentiva - emtricitabine / tenofovir disoproxil - EMEA/H/C/004137/II/0015 Zentiva k.s., Generic, Generic of Truvada, Rapporteur: Alar Irs Request for Supplementary Information adopted on 28.05.2020.	Request for supplementary information adopted with a specific timetable.
Entyvio - vedolizumab - EMEA/H/C/002782/II/0049 Takeda Pharma A/S, Rapporteur: Daniela Melchiorri Opinion adopted on 28.05.2020.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Grastofil - filgrastim - EMEA/H/C/002150/II/0029 Accord Healthcare S.L.U., Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kirsti Villikka Opinion adopted on 28.05.2020.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Grastofil - filgrastim - EMEA/H/C/002150/II/0031/G Accord Healthcare S.L.U., Rapporteur: Outi Mäki-Ikola Opinion adopted on 28.05.2020.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Hizentra - human normal immunoglobulin - EMEA/H/C/002127/II/0112/G CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 12.03.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

IDELVION - albutrepenonacog alfa - EMEA/H/C/003955/II/0037, Orphan CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 02.04.2020, 30.01.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Ilumetri - tildrakizumab - EMEA/H/C/004514/II/0012/G Almirall S.A, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 14.05.2020.	Request for supplementary information adopted with a specific timetable.
Kevzara - sarilumab - EMEA/H/C/004254/II/0022/G sanofi-aventis groupe, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 07.05.2020.	Positive Opinion adopted by consensus on 07.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Mekinist - trametinib - EMEA/H/C/002643/II/0038/G Novartis Europharm Limited, Rapporteur: Paula Boudewina van Hennik Opinion adopted on 14.05.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Nimenrix - meningococcal group a, c, w135 and y conjugate vaccine - EMEA/H/C/002226/II/0098 Pfizer Europe MA EEIG, Rapporteur: Bjorg Bolstad Request for Supplementary Information adopted on 14.05.2020.	Request for supplementary information adopted with a specific timetable.
Ogivri - trastuzumab - EMEA/H/C/004916/II/0016 Mylan S.A.S, Rapporteur: Koenraad Norga Opinion adopted on 28.05.2020.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Ondexxya - andexanet alfa - EMEA/H/C/004108/II/0010/G Portola Netherlands B.V., Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 28.05.2020, 17.04.2020.	Request for supplementary information adopted with a specific timetable.
Ozempic - semaglutide - EMEA/H/C/004174/II/0011 Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 13.02.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

POTELIGEO - mogamulizumab - EMEA/H/C/004232/II/0005/G, Orphan Kyowa Kirin Holdings B.V., Rapporteur: Paula Boudewina van Hennik Request for Supplementary Information adopted on 07.05.2020.	Request for supplementary information adopted with a specific timetable.
Prevenar 13 - pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) - EMEA/H/C/001104/II/0185/G Pfizer Europe MA EEIG, Rapporteur: Kristina Dunder Opinion adopted on 14.05.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Privigen - human normal immunoglobulin - EMEA/H/C/000831/II/0159 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 14.05.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
RoActemra - tocilizumab - EMEA/H/C/000955/II/0096 Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 14.05.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Soliris - eculizumab - EMEA/H/C/000791/II/0112, Orphan Alexion Europe SAS, Rapporteur: Jorge Camarero Jiménez Opinion adopted on 28.05.2020.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
TAKHZYRO - lanadelumab - EMEA/H/C/004806/II/0012/G, Orphan Shire Pharmaceuticals Ireland Limited, Rapporteur: Kristina Dunder Opinion adopted on 07.05.2020. Request for Supplementary Information adopted on 12.03.2020.	Positive Opinion adopted by consensus on 07.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Ultomiris - ravulizumab - EMEA/H/C/004954/II/0005 Alexion Europe SAS, Rapporteur: Jorge Camarero Jiménez Opinion adopted on 28.05.2020.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
XGEVA - denosumab - EMEA/H/C/002173/II/0071/G Amgen Europe B.V., Rapporteur: Kristina Dunder Opinion adopted on 14.05.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Zevalin - ibritumomab tiuxetan -	Request for supplementary information adopted

EMEA/H/C/000547/II/0051/G Ceft Biopharma s.r.o., Rapporteur: Sinan B. Sarac Request for Supplementary Information adopted on 28.05.2020.	with a specific timetable.
Hexacima- **EMEA/H/C/002702/WS1802/0098** **Hexaxim-** **EMEA/H/W/002495/WS1802/0103** **Hexyon-** **EMEA/H/C/002796/WS1802/0102** Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 28.05.2020.	Request for supplementary information adopted with a specific timetable.

B.5.2. CHMP assessed procedures scope: Non-Clinical and Clinical aspects

Abilify Maintena - aripiprazole - **EMEA/H/C/002755/II/0035** Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Bruno Sepodes, "update of the PI to add an alternate initiation regimen" Request for Supplementary Information adopted on 28.05.2020, 26.03.2020.	Request for supplementary information adopted with a specific timetable.
AUBAGIO - teriflunomide - **EMEA/H/C/002514/II/0029** sanofi-aventis groupe, Rapporteur: Martina Weise, "To update section 4.4 of the SmPC to add information on cases of drug-induced liver injury (DILI) observed in the post-marketing setting and section 4.8 of the SmPC to add the adverse event DILI under the frequency unknown. The package leaflet is updated accordingly." Request for Supplementary Information adopted on 14.05.2020.	Request for supplementary information adopted with a specific timetable.
Benlysta - belimumab - **EMEA/H/C/002015/II/0077** GlaxoSmithKline (Ireland) Limited, Rapporteur: Kristina Dunder, "Update of sections 4.2 and 5.1 of the SmPC in order to update the information on elderly patients based on the interim results from study BEL116559 listed as a category 3 study in the RMP; this is a meta-analysis to assess efficacy and safety in elderly subjects treated in selected belimumab studies." Opinion adopted on 28.05.2020. Request for Supplementary Information adopted	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

on 26.03.2020.	
BLINCYTO - blinatumomab - EMEA/H/C/003731/II/0036, Orphan Amgen Europe B.V., Rapporteur: Alexandre Moreau, "C.I.13: Submission of the final report from study MT103-211 classified as Category 3 Post-Authorization Safety Study (PASS) in the Risk Management Plan (RMP). This is an interventional clinical study (Open-label, Multicenter, Phase 2) to Evaluate Efficacy and Safety of the Bi-specific T cell Engager (BiTE) Antibody Blinatumomab in Adult Subjects with Relapsed/Refractory B-precursor Acute Lymphoblastic Leukemia (ALL). The objective of this PASS was to evaluate central nervous system (CNS) symptoms and explore predictive factors for CNS events associated with blinatumomab, based on an additional evaluation cohort that had been opened to help better understand CNS symptoms with blinatumomab." Opinion adopted on 28.05.2020.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Caelyx pegylated liposomal - doxorubicin - EMEA/H/C/000089/II/0094 Janssen-Cilag International NV, Rapporteur: Ondřej Slanař, "Update of sections 4.2 and 4.8 of the SmPC in line with the SmPC guideline. In addition, the MAH took the opportunity to update the PI in line with the QRD template version 10.1 and with the EDQM standard terms. Furthermore, the list of local representatives in the Package Leaflet is updated." Request for Supplementary Information adopted on 14.05.2020.	Request for supplementary information adopted with a specific timetable.
Cubicin - daptomycin - EMEA/H/C/000 Merck Sharp & Dohme B.V., Rapporteur: Bjorg Bolstad, "Update of sections 4.4 and 4.8 of the SmPC in order to include two new terms, tubulointerstitial nephritis (TIN) and drug reaction with eosinophilia and systemic symptoms (DRESS) to the Special warnings and precautions of the SmPC. TIN has also been added to the Adverse events section, based on a review of the cumulative post-marketing cases associated with the use of daptomycin. Wording has been added to the Product information with regard to the contents of sodium, implementing the guideline for	Request for supplementary information adopted with a specific timetable.

excipients in the labelling and package leaflet of medicinal products for human use. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce QRD-related, spelling, formatting and spacing corrections." Request for Supplementary Information adopted on 28.05.2020.	
Darzalex - daratumumab - EMEA/H/C/004077/II/0038, Orphan Janssen-Cilag International NV, Rapporteur: Sinan B. Sarac, "Update of section 4.8 of the SmPC in order to: -add sepsis to the list of adverse drug reactions (ADRs) with frequency common -add new data on infections and special populations following a review of relevant safety information from the daratumumab clinical program resulting in an updated Company Core Data Sheet (CCDS) based on results from a Phase 3, randomized, controlled study comparing daratumumab in combination with carfilzomib (twice weekly) and dexamethasone (DKd) with carfilzomib (twice weekly) plus dexamethasone (Kd) in subjects with relapsed/refractory multiple myeloma (study 20160275 - CANDOR) The MAH also proposes the following minor corrections. - In section 4.8 of the SPC, the ADR frequencies for Neutropenia and Back-pain were corrected. - The Package Leaflet and labelling is updated accordingly" Request for Supplementary Information adopted on 07.05.2020.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Dupixent - dupilumab - EMEA/H/C/004390/II/0030** sanofi-aventis groupe, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Kimmo Jaakkola, PRAC-CHMP liaison: Outi Mäki-Ikola, "Update of section 4.8 of the SmPC to include arthralgia as a new Adverse Drug Reaction (ADR) with a frequency not known. This is based on safety review of post-marketing data and PRAC recommendation adopted in the last PSUR assessment dated April 2020. The package leaflet is updated accordingly.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

The requested variation proposed amendments to the Summary of Product Characteristics and Package Leaflet." Opinion adopted on 14.05.2020.	
Dynastat - parecoxib - EMEA/H/C/000381/II/0077 Pfizer Europe MA EEIG, Duplicate, Duplicate of Xapit (SRD), Rapporteur: Jayne Crowe, "SmPC sections 4.3 and 4.4 are updated to include Drug Reaction with Eosinophilia and Systemic Symptoms syndrome (DRESS syndrome)." Opinion adopted on 07.05.2020.	Positive Opinion adopted by consensus on 07.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Effentora - fentanyl - EMEA/H/C/000833/II/0054/G Teva B.V., Rapporteur: Janet Koenig, "Update of the SmPC in line with the recent PSUSA evaluation outcome and to reflect the updated Company core safety information" Request for Supplementary Information adopted on 28.05.2020.	Request for supplementary information adopted with a specific timetable.
Elaprase - idursulfase - EMEA/H/C/000700/II/0086 Shire Human Genetic Therapies AB, Rapporteur: Johann Lodewijk Hillege, "Update of section 4.9 of the SmPC in order to include a warning on the risk of anaphylactoid reaction following overdose with elaprase." Opinion adopted on 28.05.2020.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
EVRA - ethinylestradiol / norelgestromin - EMEA/H/C/000410/II/0046/G Janssen-Cilag International NV, Rapporteur: Paula Boudewina van Hennik, "Update of section 4.5 of the SmPC in order to add drug-drug interaction information on use with cobicistat, following the update of the company's core data sheet (CCDS) due to new data. The Package Leaflet is updated accordingly." Opinion adopted on 28.05.2020. Request for Supplementary Information adopted on 26.03.2020.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Fabrazyme - agalsidase beta - EMEA/H/C/000370/II/0116 Genzyme Europe BV, Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.2 and 5.1 of the SmPC in order to change posology recommendations in adults, children and adolescents aged 8 years and older by removing the information on the lower dosing regimens	See agenda 9.1 Request for supplementary information adopted with a specific timetable.

that have been used in clinical studies and update the clinical information based on the review of published scientific literature including 3 observational studies in patients remaining on standard dose of Fabrazyme or switching to low-dose Fabrazyme (0.5 mg/kg every 2 weeks) or to the registered dose of agalsidase alfa (0.2 mg/kg every 2 weeks). In addition, the MAH took the opportunity to propose changes in the Product Information according to the QRD templates and current guidelines, including new warnings related to sodium excipient and traceability of biological medicinal products." Request for Supplementary Information adopted on 28.05.2020.	
Fotivda - tivozanib - EMEA/H/C/004131/II/0012 EUSA Pharma (Netherlands) B.V., Rapporteur: Bruno Sepodes, "Submission of AV-951-15-303 (TIVO-3) study (Phase 3 randomized, controlled, multi-centre, open-label study to compare tivozanib versus sorafenib in RCC patients who have failed 2 or 3 prior systemic regimens) in order to present the second interim OS analysis and to fulfil PAM LEG-003 procedure." Request for Supplementary Information adopted on 28.05.2020.	Request for supplementary information adopted with a specific timetable.
Galafold - migalastat - EMEA/H/C/004059/II/0025, Orphan Amicus Therapeutics Europe Limited, Rapporteur: Johann Lodewijk Hillege, "Update to the Galafold Summary of Product Characteristics (SmPC), section 5.1 Pharmacodynamic Properties to add 1017 new amenable mutations in Table 2: Galafold (migalastat) amenability table and delete the entire Table 3: Mutations not amenable to Galafold (migalastat). In addition, the MAH took the opportunity to update contact details of the MAH and Belgium local representatives and the Labelling (outer packaging), section 5. Method and Route(s) of administration as well as Package Leaflet, section 3. How to take Galafold in order to improve the instructions for opening and removal of the capsules out of the packaging. Editorial linguistic changes are made in Czech, Dutch, Finnish, Greek, Polish, Icelandic, Italian and Swedish languages."	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Opinion adopted on 14.05.2020.	
Glivec - imatinib - EMEA/H/C/000406/II/0117 Novartis Europharm Limited, Rapporteur: Jorge Camarero Jiménez, "Update of section 4.6 of the SmPC to include that women of childbearing potential must be advised to use effective contraception and stop breast-feeding during treatment and for at least 15 days after stopping treatment with imatinib, based on a company review of the company Core Data Sheet. The PL has been updated accordingly." Opinion adopted on 28.05.2020. Request for Supplementary Information adopted on 26.03.2020, 30.01.2020, 10.10.2019.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
IDELVION - albutrepenonacog alfa - EMEA/H/C/003955/II/0034, Orphan CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus, "Submission of a variation to update the dosing regimen as follows: -21-day prophylaxis regimen with rIX-FP at a dose of 100 IU/kg body weight for patients ≥ 12 years who are well controlled on a 14-day prophylaxis regimen. -10- or 14-day prophylaxis regimen with rIX-FP at a dose of 75 IU/kg body weight for patients < 12 years who are well controlled on a 7-day prophylaxis regimen. This submission also updates the existing population PK model with additional intravenous and subcutaneous (SC) data from the PTPs in the PTP arm of study CSL654_3003 and re-evaluates the covariates that are possible determinants of PK variability." Opinion adopted on 28.05.2020. Request for Supplementary Information adopted on 26.03.2020, 14.11.2019.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Kalydeco - ivacaftor - EMEA/H/C/002494/II/0084, Orphan Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Maria Concepcion Prieto Yerro, "Update of section 5.1 of the SmPC in order to include the information based on results from study VX14-661-110, which is a Phase 3, multicenter, open label, rollover study for Studies 103, 106, 107, 108, 109, 111, 112, and 114 designed to evaluate the long-term safety and tolerability of TEZ/IVA treatment in combination with ivacaftor for 96 weeks in	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

cystic fibrosis (CF) subjects 12 years and older, homozygous or heterozygous for the F508del CFTR mutation." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 12.03.2020.	
Nerlynx - neratinib - EMEA/H/C/004030/II/0011/G Pierre Fabre Medicament, Rapporteur: Bruno Sepodes, "Update of sections 4.2, 4.3, 4.4, 4.5 and 5.2 of the SmPC in order to update the pharmacokinetics properties of neratinib and amend drug-drug interaction (DDI) information with CYP3A4/P-gp inducers and inhibitors based on two ADME studies (PUMA-NER-0105 and PUMA-NER-0102), a PBPK model report and in vitro studies; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to make minor corrections to the PI and to bring the PI in line with the latest QRD template version 10. Update of sections 4.2, 4.3, 4.4, 4.5 and 5.2 of the SmPC in order to update DDI information with H2-receptor antagonists and add DDI information with loperamide based on two DDI studies (PUMA-NER-0104, PUMA-NER-0103); the Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 28.05.2020.	Request for supplementary information adopted with a specific timetable.
Ondexxya - andexanet alfa - EMEA/H/C/004108/II/0003 Portola Netherlands B.V., Rapporteur: Jan Mueller-Berghaus, "Submission of the final report from Population PK and PK/PD Modelling Report (POR-PKPD-ADEX-321) listed as a category 2 study in the RMP/Specific Obligation 004 in Annex II." Request for Supplementary Information adopted on 28.05.2020, 12.12.2019.	Request for supplementary information adopted with a specific timetable.
Pradaxa - dabigatran etexilate - EMEA/H/C/000829/II/0123 Boehringer Ingelheim International GmbH, Rapporteur: Mark Ainsworth, "Update of section 4.8 of the SmPC in order to update the safety information regarding neutropenia and agranulocytosis following update to the Pradaxa Company Core Data Sheet. The Package Leaflet are updated accordingly. In addition, the Marketing authorisation holder (MAH) took the	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

opportunity to make Minor Linguistic Changes to the several language versions of the Product Information." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 12.03.2020.	
PREVYMIS - letermovir - EMEA/H/C/004536/II/0016/G, Orphan Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson, "C.I.4 (type II) – Update of sections 4.2, 4.4, 6.2 and 6.6 of the SmPC to include the requirement to use an in-line filter at the point of administration, and avoid the use of the medicinal product with IV bags and infusion set materials containing polyurethane or the plasticizer diethylhexyl phthalate (DEHP), for finished product Prevymis 240 mg and 480 mg concentrate for solution for infusion (EU/1/17/1245/003-004). The package leaflet and labelling are updated accordingly. B.II.d.1.z (type IB) C.1.11.z (type IB) - Change in the due date of the Annex II condition for the medicinal product Prevymis 240 mg and 480 mg concentrate for solution for infusion (EU/1/17/1245/003-004) . The MAH took the opportunity to relocate the information regarding to sodium content in the PREVYMIS 240 mg/ 480 mg film-coated tablets (EU/1/17/1245/001-002) from section 2 to section 4.4 of the SmPC and to slightly update the description of the packaging from section 6.5 of the SmPC." Opinion adopted on 28.05.2020. Request for Supplementary Information adopted on 26.03.2020, 12.12.2019.	See agenda 9.1 Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Replagal - agalsidase alfa - EMEA/H/C/000369/II/0106 Shire Human Genetic Therapies AB, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Liana Gross-Martirosyan, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Update of section 4.8 of the Summary of Product Characteristics (SmPC) in order to update the list of adverse drug reactions (ADRs) information based on the final results from study HGT-REP-081 " a Multicenter Open-label Treatment Protocol to Observe the Safety of Replagal (agalsidase alfa) Enzyme Replacement Therapy in Canadian Patients with Fabry Disease". In addition, the MAH took the opportunity to introduce editorial	Request for supplementary information adopted with a specific timetable.

and QRD changes in sections throughout the Product Information according to the QRD templates and current guidelines, including new warnings related to sodium excipient and traceability of biological medicinal products. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 14.05.2020.	
Qutenza - capsaicin - EMEA/H/C/000909/II/0049 Grunenthal GmbH, Rapporteur: Bruno Sepodes, "Update of section 4.8 of the SmPC in order to update the safety information on adverse reactions frequencies based on latest clinical data pooling; the Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to bring the PI in line with the latest QRD template version." Request for Supplementary Information adopted on 14.05.2020, 19.03.2020.	Request for supplementary information adopted with a specific timetable.
Reyataz - atazanavir / atazanavir sulfate - EMEA/H/C/000494/II/0129/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Jean-Michel Race, "Grouped application: - C.I.4 (Type IB) - Update of sections 4.3 and 4.5 of the SmPC to add a new contraindication and a new drug-drug interaction related to co-administration with lomitapide, based on recommendations already approved for lomitapide; the Package Leaflet is updated accordingly. - C.I.4 (Type II) - Update of section 4.5 of the SmPC to add a new drug-drug interaction related to co-administration with direct oral anticoagulants (DOACs), to align with wording approved for DOACs; the Package Leaflet is updated accordingly. In addition, the Marketing Authorisation Holder (MAH) took the opportunity to update the PI in line with the Annex to the European Commission guideline on `Excipients in the labelling and package leaflet of medicinal products for human use' (EMA/CHMP/302620/2017 Rev.1) regarding sucrose content, remove boceprevir from section 4.5 of the SmPC and section 2 of the PL, bring the PI in line with the latest QRD template version 10.1 and update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 28.05.2020.	
Rubraca - rucaparib - EMEA/H/C/004272/II/0019/G Clovis Oncology Ireland Limited, Rapporteur: Jorge Camarero Jiménez, "Submission of the final report from study CO-338-017 (ARIEL2), a Phase 2, open-label, study evaluating the efficacy and safety of rucaparib in patients with relapsed high-grade serous or endometrioid epithelial ovarian, fallopian tube, or primary peritoneal cancer. Submission of the final report from study CO-338-010 (Study 10), a Phase 1/2, open-label study evaluating the safety, PK and efficacy of rucaparib in patients with relapsed platinum-sensitive high grade ovarian cancer." Opinion adopted on 28.05.2020.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Signifor - pasireotide - EMEA/H/C/002052/II/0046, Orphan Recordati Rare Diseases, Rapporteur: Kristina Dunder, "Update of sections 4.4 of the SmPC in order to add new warnings on cholangitis and ketoacidosis and 4.8 to add diabetic ketoacidosis to the list of adverse drug reactions (ADRs) with frequency not known. The Package Leaflet is updated accordingly." Opinion adopted on 14.05.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Soliris - eculizumab - EMEA/H/C/000791/II/0113, Orphan Alexion Europe SAS, Rapporteur: Jorge Camarero Jiménez, "Submission of a variation to update section 4.2 of the SmPC to include home-infusion as an alternative infusion setting for Soliris for all the approved indications (paroxysmal nocturnal hemoglobinuria, atypical hemolytic uremic syndrome, refractory generalized myasthenia gravis and neuromyelitis optica spectrum disorder). The PL has been updated accordingly." Opinion adopted on 28.05.2020.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Stribild - elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil - EMEA/H/C/002574/II/0111/G Gilead Sciences Ireland UC, Rapporteur: Bruno Sepodes, "Grouped application: - C.I.4 (Type II): Update of section 4.5 of the SmPC to include data on the drug-drug interaction between Stribild and the thienopyridine anti-platelet drugs clopidogrel	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

and prasugrel, based on a MAH cumulative safety review. The Package Leaflet is updated accordingly. - C.I.4 (Type II): Update of section 4.5 of the SmPC to include data on the drug-drug interaction between Stribild and medicinal products or oral supplements containing polyvalent cations, based on a MAH cumulative safety review. The Package Leaflet is updated accordingly. - C.I.3.z (Type IBz): Update of sections 4.5 and 4.8 of the SmPC to implement information related to the interaction with didanosine, and section 4.8 of the SmPC to implement new wording regarding lactic acidosis, in line with the PRAC recommendation from EMEA/H/C/PSUSA/00002892/201903. In addition, the Marketing Authorisation Holder (MAH) took the opportunity to correct the amount of lactose stated in section 2 of the SmPC, update section 4.5 of the SmPC in line with the clinical study report for Study GS-US-216-0125, update the PI in line with the Annex to the European Commission guideline on `Excipients in the labelling and package leaflet of medicinal products for human use' (EMA/CHMP/302620/2017 Rev.1) regarding sodium content and make minor editorial changes to the PI. Furthermore, the PI is brought in line with the latest QRD template version 10.1." Opinion adopted on 14.05.2020.	
Tegsedi - inotersen - EMEA/H/C/004782/II/0011, Orphan Akcea Therapeutics Ireland Limited, Rapporteur: Martina Weise, "Update of SmPC section 5.3 to reflect the results of rat carcinogenicity study." Request for Supplementary Information adopted on 28.05.2020.	Request for supplementary information adopted with a specific timetable.
Tygacil - tigecycline - EMEA/H/C/000644/II/0110 Pfizer Europe MA EEIG, Rapporteur: Jorge Camarero Jiménez, "Update of sections 4.4 and 4.8 of the SmPC in order to add a recommendation regarding monitoring of coagulation parameters prior to and during tigecycline treatment based on post-marketing data and to update the frequency of the existing adverse drug reaction hypofibrinogenaemia from 'Not known' to 'Rare'. The Package Leaflet	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

is updated accordingly. In addition, the Marketing Authorisation Holder (MAH) took the opportunity to update the PI in line with the Annex to the European Commission guideline on `Excipients in the labelling and package leaflet of medicinal products for human use' (EMA/CHMP/302620/2017 Rev.1) regarding sodium content and to bring the PI in line with the latest QRD template version 10.1." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 12.03.2020.	
Tysabri - natalizumab - EMEA/H/C/000603/II/0117 Biogen Netherlands B.V., Rapporteur: Jan Mueller-Berghaus, "C.I.4 Update of section 5.2 of the SmPC in order to update pharmacokinetic information based on an updated PK analysis from 11 studies (both IV and SC administration) and data with serial PK sampling as measured by an industry standard assay." Request for Supplementary Information adopted on 28.05.2020.	Request for supplementary information adopted with a specific timetable.
Vemlidy - tenofovir alafenamide - EMEA/H/C/004169/II/0023 Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, "Update of sections 4.4, 4.8, 5.1 and 5.2 of the SmPC based on interim analysis data at Week 24 from study GS-US-320-4035. This is a Phase 2, open-label study evaluating the efficacy and safety of tenofovir alafenamide (TAF) in virologically suppressed chronic hepatitis B subjects with renal and/or hepatic impairment who switch from tenofovir disoproxil fumarate and/or other oral antiviral agents to TAF 25 mg once daily. Supportive safety and pharmacokinetic data are also provided from Study GS-US-292-1825 (phase 3b trial in which elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide an fixed-dose TAF containing combination indicated for the treatment of HIV-1 infection, was evaluated in HIV-1 infected subjects with end stage renal disease). Study GS-US-320-4035 is included in the RMP version 4.2 under additional PhV activities." Request for Supplementary Information adopted on 07.05.2020, 06.02.2020.	Request for supplementary information adopted with a specific timetable.
Vfend - voriconazole - EMEA/H/C/000387/II/0137/G	Request for supplementary information adopted with a specific timetable.

Pfizer Europe MA EEIG, Rapporteur: Johann Lodewijk Hillege, "Grouping of two type II variations: -to update section 4.4 of the SmPC in order to add a new warning on adrenal events, along with editorial changes to the paragraph and the abbreviation of severe cutaneous adverse reactions (SCARs), -to update section 4.5 of the SmPC in order to add drug-drug interaction information with naloxegol, ivacaftor and corticosteroids following PRAC request during the assessment of PSUR 18 (for corticosteroids) and the French National Agency for the Safety of Medicines and Health Products (ANSM) update of the French "Medical Interaction Thesaurus" (May 2018), where voriconazole is classified as a strong CYP3A4 inhibitor. In addition, the MAH has taken the opportunity to update the information in the SmPC in line with the EU excipient guidance from October 2017 (SANTE-2017-11668) for sodium and cyclodextrin, to introduce a correction to the amount of sodium per vial for the IV presentations in sections 2. QUALITATIVE AND QUANTITATIVE COMPOSITION and 4.4 Special warnings and precautions for use of the SmPC. The Package Leaflet is updated accordingly. Following a recent discussion with EMA/EDQM; the MAH is also updating Annex IIIA Outer carton text for both iv presentations 16. INFORMATION IN BRAILLE to include: "Justification for not including Braille accepted." In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.1." Request for Supplementary Information adopted on 14.05.2020.	
Xermelo - telotristat ethyl - EMEA/H/C/003937/II/0014, Orphan Ipsen Pharma, Rapporteur: Martina Weise, "To update sections 4.2 and 5.2 of the SmPC following final results from study LX1606-111; this is a Phase 1, open-label, parallel-group study to evaluate the single-dose pharmacokinetics of Telotristat Ethyl in Male and Female Subjects with Severe Hepatic Impairment and Matched Subjects with Normal Function; the Package Leaflet is updated accordingly. Additionally, the MAH took the	Positive Opinion adopted by consensus on 07.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

opportunity to include minor editorial updates to the PL." Opinion adopted on 07.05.2020. Request for Supplementary Information adopted on 16.01.2020, 14.11.2019, 19.09.2019, 11.07.2019.	
WS1779 **Thymanax-EMEA/H/C/000916/WS1779/0044** **Valdoxan-EMEA/H/C/000915/WS1779/0046** Upjohn EESV, Lead Rapporteur: Bjorg Bolstad, "Update of section 4.8 of the SmPC to add 'Myalgia' with a frequency 'uncommon' following routine pharmacovigilance review. The Package Leaflet section 4 is updated accordingly. In addition, the WorkShare Applicant takes the opportunity to bring the Product Information of Valdoxan and Thymanax in line with the latest QRD template version 10.1." Opinion adopted on 07.05.2020.	Positive Opinion adopted by consensus on 07.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1798 **Lyrica-EMEA/H/C/000546/WS1798/0104** **Pregabalin Pfizer-EMEA/H/C/003880/WS1798/0033** Pfizer Europe MA EEIG, Lead Rapporteur: Johann Lodewijk Hillege, "Update section 4.8 and section 5.1 of the SmPC to reflect data from study A0081106 "A 12-Month Open-Label Study to Evaluate the Safety and Tolerability of Pregabalin as Adjunctive Therapy in Pediatric Subjects 1 Month to 16 Years of Age With Partial Onset Seizures and Pediatric and Adult Subjects 5 to 65 Years of Age With Primary Generalized Tonic-Clonic Seizures"" Request for Supplementary Information adopted on 07.05.2020.	Request for supplementary information adopted with a specific timetable.

B.5.3. CHMP-PRAC assessed procedures

Bavencio - avelumab - EMEA/H/C/004338/II/0013 Merck Europe B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Hans Christian Siersted, "Update of section 5.1 of the SmPC in order to update efficacy information following results from study EMR100070-003 Part B listed as a specific obligation in the Annex II; this is a	See agenda 9.1 Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Phase II, open-label, multicenter trial to investigate the clinical activity and safety of avelumab (MSB0010718C) in subjects with Merkel cell carcinoma. With this submission the company is also taking the opportunity to update annex-II proposing deletion of the specific obligation and proposing the switch from conditional to full marketing authorisation. The package leaflet and the RMP (version 2.1) are updated accordingly." Opinion adopted on 28.05.2020. Request for Supplementary Information adopted on 27.02.2020.	
Bortezomib Fresenius Kabi - bortezomib - EMEA/H/C/005074/II/0001/G Fresenius Kabi Deutschland GmbH, Generic, Generic of VELCADE, Rapporteur: Kolbeinn Gudmundsson, PRAC Rapporteur: Amelia Cupelli Request for Supplementary Information adopted on 28.05.2020, 26.03.2020.	Request for supplementary information adopted with a specific timetable.
Caprelsa - vandetanib - EMEA/H/C/002315/II/0043 Genzyme Europe BV, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Adrien Inoubli, "C.I.4 Update of section 5.1 of the SmPC in order to update pharmacodynamic information based on interim results from study D4200C00104, listed as a specific obligation in the Annex II. This is an observational study (including a retrospective arm to evaluate the Benefit/Risk of vandetanib (Caprelsa) 300 mg in RET mutation negative and RET mutation positive patients with symptomatic, aggressive, sporadic, unresectable, locally advanced/metastatic thyroid cancer (MTC)), to confirm the efficacy and safety of Caprelsa in RET-negative patients with the aim to fulfil SOB001 and convert Caprelsa from conditional to normal Marketing Authorization. In addition the MAH takes to opportunity to rectify the Dutch translation of the Caprelsa Product Information." Request for Supplementary Information adopted on 28.05.2020.	Request for supplementary information adopted with a specific timetable.
Cervarix - human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed) - EMEA/H/C/000721/II/0106 GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke, PRAC Rapporteur: Jean-	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Michel Dogné, "Update of sections 4.4 and 5.1 of the SmPC based on final results from study HPV-019 listed as a category 3 study in the RMP (in fulfilment of MEA080); this is a safety and immunogenicity study of Cervarix in HIV-positive female subjects aged 15-25 years as compared to HPV-4, which was already submitted in P46-95. In addition, the Marketing authorisation holder (MAH) took the opportunity to reflect an update in section 4.2 of the SmPC to indicate that limited clinical data is now available in 4-6 years old children based on study HPV-073 following assessment in P46-90; this is a safety and immunogenicity study of Cervarix in girls aged 4-6 years, as an alternative to the current adolescent HPV vaccination schedule. The RMP version 21 has also been submitted to reflect the availability of the final results of the HPV-019 and HPV-073 studies, and the use of Cervarix in HIV-infected subjects or subjects with known immune deficiencies has been removed as missing information. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.1." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 12.03.2020.	
Cyramza - ramucirumab - EMEA/H/C/002829/II/0038 Eli Lilly Nederland B.V., Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to add posterior reversible encephalopathy syndrome (PRES) and dysphonia as a warning and as undesirable effect, respectively. The Labelling and Package Leaflet are updated accordingly. The RMP version 9.3 has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template." Opinion adopted on 28.05.2020. Request for Supplementary Information adopted on 26.03.2020.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Firmagon - degarelix - EMEA/H/C/000986/II/0037 Ferring Pharmaceuticals A/S, Rapporteur:	Request for supplementary information adopted with a specific timetable.

Alexandre Moreau, PRAC Rapporteur: Adrien Inoubli, "C.I.11.b update of Annex II to revise risk minimisation measures based on previous and a newly submitted study. As a consequence, the RMP is updated accordingly. The MAH took the occasion to transfer to GVP V revision 2 of the RMP, to align the PI to QRD template v.10.1 and propose combination of different strengths." Request for Supplementary Information adopted on 14.05.2020.	
Kisqali - ribociclib - EMEA/H/C/004213/II/0021 Novartis Europharm Limited, Rapporteur: Filip Josephson, PRAC Rapporteur: Hans Christian Siersted, "Update of sections 4.2 and 4.4 of the SmPC in order to add a warning on ILD/pneumonitis and related dose modification recommendations. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to make minor corrections to the SmPC, bring the PI in line with the latest QRD template version 10.1 and update the list of local representatives in the Package leaflet. The RMP version 4.2 is approved." Opinion adopted on 28.05.2020. Request for Supplementary Information adopted on 27.02.2020.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
NexoBrid - concentrate of proteolytic enzymes enriched in bromelain - EMEA/H/C/002246/II/0047, Orphan MediWound Germany GmbH, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Submission of the final report from study MW2013-06-01, listed as a category 3 study in the RMP. This is an international, observational retrospective, data-collection study assessing efficacy of applied risk-minimisation measures in burn patients treated with NexoBrid. The RMP version 7.0 has also been submitted. In addition, the MAH took the opportunity to revise the RMP in line with the new RMP template (GVP Rev. 2) and to change the due date for the following category 3 studies: MW2013-06-01 and MW2010-03-02 (DETECT)" Request for Supplementary Information adopted on 14.05.2020.	Request for supplementary information adopted with a specific timetable.
ProQuad - measles, mumps, rubella and	Positive Opinion adopted by consensus on

varicella vaccine (live) - EMEA/H/C/000622/II/0139 MSD Vaccins, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski, "To update sections 4.4 and 4.8 of the SmPC to update the safety information and further characterize the risk of secondary transmission following MAH evaluation of new significant Pharmacovigilance data. The Package Leaflet is updated accordingly. The RMP has been updated to version 7.1 to reflect those changes and with the consequential revisions: the important potential risk of "potential secondary transmission of Oka/Merck varicella vaccine virus strain in susceptible high-risk individuals leading to severe clinical consequences" is renamed to "secondary transmission of Oka/Merck varicella vaccine virus strain in susceptible individuals leading to disseminated disease" and is reclassified to important identified risk. The MAH takes the opportunity to implement some changes in section 6.5 of the SmPC with information on the glass type for the immediate container following the "Excipients in the labelling and package leaflet of medicinal products for human use guideline" and the "Guideline on quality aspects included in the product information for vaccines for human use". Annex A has been updated with the same information. In addition, the MAH implements QRD v10.1 taking into account the 'Compilation of QRD decisions on stylistic matters in product information'. The MAH also takes the chance to align some wordings across other MMRV vaccines owned by the MAH, in particular section 6.6 'Special precautions for disposal and other handling'." Opinion adopted on 14.05.2020.	14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Resolor - prucalopride - EMEA/H/C/001012/II/0051 Shire Pharmaceuticals Ireland Limited, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, "Update of the RMP on the patients' exposure based on post-marketing reports. In addition, the MAH took the opportunity to make minor editorial changes to the SmPC and RMP."	Request for supplementary information adopted with a specific timetable.

Opinion adopted on 25.06.2020. Request for Supplementary Information adopted on 14.05.2020.	
SCENESSE - afamelanotide - EMEA/H/C/002548/II/0033, Orphan Clinuvel Europe Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Update of section 4.8 of the SmPC to revise the frequencies of adverse drug reactions (ADRs) based on safety reports and to add new ADRs based on post-marketing spontaneous reports as requested during Scenesse Renewal procedure (EMEA/H/C/002548/R/0026); the Package Leaflet is updated accordingly. The RMP version 9.0 (in line with rev 2 of the template) has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes in section 2 of the SmPC and Annex IIIA." Request for Supplementary Information adopted on 14.05.2020.	Request for supplementary information adopted with a specific timetable.
Symkevi - tezacaftor / ivacaftor - EMEA/H/C/004682/II/0016, Orphan Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Rhea Fitzgerald, "Update of sections 4.8 and 5.1 of the SmPC in order to update the information based on final results from study VX14-661-110 listed as a category 3 study in the RMP; this is a Phase 3, multicenter, open label, rollover study for Studies 103, 106, 107, 108, 109, 111, 112, and 114 designed to evaluate the long-term safety and tolerability of TEZ/IVA treatment for 96 weeks in cystic fibrosis (CF) subjects 12 years and older, homozygous or heterozygous for the F508del CFTR mutation. In addition, the Marketing authorisation holder (MAH) took the opportunity to bring the PI in line with the latest QRD template version 10.1. The RMP version 2.2 has also been submitted." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 13.02.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Talzenna - talazoparib - EMEA/H/C/004674/II/0001 Pfizer Europe MA EEIG, Rapporteur: Filip Josephson, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, "Update of	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

sections 4.2 and 5.2 of the SmPC in order to change posology recommendations in patients with severe renal impairment and update pharmacokinetic information based on the results from PK study MDV3800-01 (C3441001) listed as a category 3 study in the RMP. The RMP version 1.0 has also been submitted. In addition, the MAH took the opportunity to make minor changes through the product information and to bring the PI in line with the latest QRD template version 10.1." Opinion adopted on 28.05.2020. Request for Supplementary Information adopted on 26.03.2020.	
TECFIDERA - dimethyl fumarate - EMEA/H/C/002601/II/0063 Biogen Netherlands B.V., Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, "Update of sections 4.4 and 4.8 of the SmPC to reflect PML in the setting of mild lymphopenia based on data submitted in the ongoing PSUSA/00010143/201903. The Package Leaflet is updated accordingly. Additionally, the Product Information has been updated in line with QRD template (version 10.1)." Request for Supplementary Information adopted on 28.05.2020, 30.01.2020, 19.09.2019.	See agenda 9.1 Request for supplementary information adopted with a specific timetable.
Tremfya - guselkumab - EMEA/H/C/004271/II/0020 Janssen-Cilag International N.V., Rapporteur: Melinda Sobor, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Update of sections 4.4 and 4.8 of the SmPC to include anaphylaxis as an adverse drug reaction (ADR) with a frequency uncommon. Additionally, the ADR "injection site erythema" is amended to reflect injection site reactions in more general terms. The package leaflet is updated accordingly. Furthermore, the RMP is updated to version 5.3." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 12.03.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Trumenba - meningococcal group B vaccine (recombinant, adsorbed) - EMEA/H/C/004051/II/0023 Pfizer Europe MA EEIG, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Jean-Michel Dogné, "Update of sections 4.8 and 5.1 of the	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

SmPC in order to update the safety and immunogenicity information based on final results from study B1971033 listed as a category 3 study in the RMP (MEA007); this is a duration of immunity study to assess persistence of hSBA response for up to 48 months after completion of vaccination with Trumenba and the immunogenicity, safety, and tolerability of a booster dose of Trumenba. The RMP version 3.0 has also been submitted, including changes related to this variation, changes agreed during another ongoing variation (II-13) and editorial changes. In addition, the Marketing authorisation holder (MAH) took the opportunity to include editorial changes in Annex II, in the labelling and in the Package Leaflet." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 12.03.2020.	
Velphoro - iron - EMEA/H/C/002705/II/0021 Vifor Fresenius Medical Care Renal Pharma France, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Kimmo Jaakkola, "Update of section 5.1 of the SmPC in order to add information related to the results of the VERIFIE study. This was a non-interventional voluntary PASS trial, which aimed to investigate the short and long-term real-life safety, effectiveness, and adherence of Velphoro in patients with hyperphosphataemia undergoing haemodialysis or peritoneal dialysis. It was listed as an additional pharmacovigilance activity (EMEA/H/C/002705/MEA/002), a category 3 study in the RMP. Furthermore, minor editorial wording changes in section 4.2 to provide consistent information between the SmPC and that already existing in the Labelling and PL were introduced. The RMP version 8.0 has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to bring the PI in line with the latest QRD template version 10.1." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 12.03.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

B.5.4. PRAC assessed procedures

PRAC Led **Duavive - estrogens conjugated / bazedoxifene - EMEA/H/C/002314/ II/0024** Pfizer Europe MA EEIG, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Update of the Risk Management Plan (RMP) to V3.0, to include amended study milestones and to revise the RMP document format in line with latest Good Pharmacovigilance Practices Guidance Module V, revision 2 guidelines, as requested during the assessment of the renewal." Request for Supplementary Information adopted on 14.05.2020.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Flixabi - infliximab - EMEA/H/C/004020/II/0052** Samsung Bioepis NL B.V., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Update of the RMP to replace the prospective observational cohort study of Flixabi in patients with Crohn's disease (CD) (SB2-G42-CD), with real-world data from PERFUSE, CREDIT and CEDUR studies." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 12.03.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Kineret - anakinra - EMEA/H/C/000363/II/0073** Swedish Orphan Biovitrum AB (publ), Rapporteur: Mark Ainsworth, PRAC Rapporteur: Hans Christian Siersted, PRAC-CHMP liaison: Sinan B. Sarac, "Submission of the final report from study (Sobi.ANAKIN-302) listed as a category 3 study in the RMP and in accordance with Article 46 of Regulation (EC) No 1901/2006. This is a non-interventional, post-authorisation safety study to evaluate long-term safety of anakinra (Kineret) in patients with systemic juvenile idiopathic arthritis. The RMP version 5.3 has also been updated to reflect the completion of the study." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 12.03.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

PRAC Led **Moventig - naloxegol - EMEA/H/C/002810/II/0029/G** Kyowa Kirin Holdings B.V., Rapporteur: Bart Van der Schueren, PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Peter Kiely, "Submission of an updated RMP version 6 in order to update the list of safety concerns" Request for Supplementary Information adopted on 14.05.2020.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Naglazyme - galsulfase - EMEA/H/C/000640/II/0081** BioMarin International Limited, Rapporteur: Fátima Ventura, PRAC Rapporteur: Ana Sofia Diniz Martins, PRAC-CHMP liaison: Fátima Ventura, "Submission of an updated RMP version 6.0 in order to update the safety specification plan based on a review of the preclinical, clinical, post-marketing and literature data. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the Naglazyme RMP to the latest EU RMP template." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 12.03.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Retacrit - epoetin zeta - EMEA/H/C/000872/II/0094** Pfizer Europe MA EEIG, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Pfizer's biosimilar epoetin zeta list of safety concerns has been aligned to the Innovator's Eprex (reference product, INN epoetin alfa)." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 13.02.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Spectrila - asparaginase - EMEA/H/C/002661/II/0017** medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Andrea Laslop, PRAC Rapporteur: Jan Neuhauser, PRAC-CHMP liaison: Andrea Laslop, "Update of the Risk Management Plan (version 12) for Spectrila in accordance with GVP Module V Rev 2 including the implementation of the new RMP	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

template and the new definition of safety concerns. The QPPV and the Milestones / Timelines for the clinical study MC-Spectrila.1/ALL were updated in accordance to the newly applied DLP for this Risk Management Plan." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 17.04.2020.	
PRAC Led **Tybost - cobicistat - EMEA/H/C/002572/II/0054** Gilead Sciences Ireland UC, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Ana Sofia Diniz Martins, PRAC-CHMP liaison: Bruno Sepodes, "Update of sections 4.4 and 4.5 of the SmPC in order to add a new contraindication regarding drug-drug interactions between cobicistat-containing products and thienopyridines. The proposed addition is based on a cumulative safety review conducted by MAH and related to the Pharmacovigilance Risk Assessment Committee recommendation dated June 2019 with regards to the interaction of clopidogrel with boosted antiviral HIV therapy leading to insufficient inhibition of platelet aggregation. In addition, the MAH took also the opportunity to amend the amount of sunset yellow FCF aluminium lake (E110) per tablet in section 2 of the SmPC following the suggestion done by EMA Labelling group during the renewal application (EMEA/H/C/002572/R/0041). Moreover, the sodium excipient wording is added in accordance with the "Excipients in the labelling and package leaflet of medicinal products for human use" (SANTE-2017-11668). Finally, some minor linguistic amendments are also implemented. The Package Leaflet is updated accordingly." Opinion adopted on 14.05.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Xadago - safinamide - EMEA/H/C/002396/II/0035** Zambon S.p.A., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Peter Kiely, "C.I.13 - Results of a DUS and changes to RMP." Request for Supplementary Information adopted on 14.05.2020.	Request for supplementary information adopted with a specific timetable.

PRAC Led **WS1742** **Ebymect-EMEA/H/C/004162/WS1742/0043** **Edistride-EMEA/H/C/004161/WS1742/0037** **Forxiga-EMEA/H/C/002322/WS1742/0056** **Xigduo-EMEA/H/C/002672/WS1742/0054** AstraZeneca AB, Lead Rapporteur: Kristina Dunder, Lead PRAC Rapporteur: Annika Folin, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final results of a Post-Authorization Safety Study (listed as a category 3 study in the RMPs): meta-analysis across studies D1690C00018, D1690C00019 and D1693C00001 (DECLARE), for analysis of lower limb amputation and relevant preceding adverse events. These three studies include T2DM patients with established CVD or with CVD risk factors treated with dapagliflozin or placebo in clinical trial settings. The updated dapagliflozin RMP version 19.3 and dapagliflozin/metformin fixed dose combination (FDC) RMP version 12.3 were agreed during the procedure." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 12.03.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **WS1760** **Lixiana-EMEA/H/C/002629/WS1760/0024** **Roteas-EMEA/H/C/004339/WS1760/0011** Daiichi Sankyo Europe GmbH, Lead Rapporteur: Maria Concepcion Prieto Yerro, Lead PRAC Rapporteur: Adrien Inoubli, PRAC-CHMP liaison: Alexandre Moreau, "Submission of the final study report from study ETNA-DUS: a retrospective drug utilisation chart review study listed as a category 3 study in the RMP. The Edoxaban Treatment in Routine Clinical Practice Drug Utilisation Study (ETNA-DUS) was designed to gain insight on how edoxaban is used in real practice. The ETNA-DUS intends to help identify prescription patterns and the effectiveness of the educational programs" Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 14.05.2020, 16.01.2020.	

B.5.5. CHMP-CAT assessed procedures

Alofisel - darvadstrocel - EMEA/H/C/004258/II/0016/G, Orphan, ATMP Takeda Pharma A/S, Rapporteur: Lisbeth Barkholt, CHMP Coordinator: Kristina Dunder Opinion adopted on 28.05.2020, 20.05.2020.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Kymriah - tisagenlecleucel - EMEA/H/C/004090/II/0021/G, Orphan, ATMP Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang Opinion adopted on 28.05.2020, 20.05.2020.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Spherox - spheroids of human autologous matrix-associated chondrocytes - EMEA/H/C/002736/II/0015, ATMP CO.DON AG, Rapporteur: Lisbeth Barkholt, CHMP Coordinator: Kristina Dunder, "Update of sections 4.8 and 5.1 of the SmPC following the 48-month follow up data for trial cod 16 HS 13, a study assessing the long-term efficacy and safety of Spherox." Opinion adopted on 28.05.2020, 20.05.2020. Request for Supplementary Information adopted on 24.04.2020.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

B.5.6. CHMP-PRAC-CAT assessed procedures

Strimvelis - autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence - EMEA/H/C/003854/II/0026, Orphan, ATMP Orchard Therapeutics (Netherlands) BV, Rapporteur: Sol Ruiz, CHMP Coordinator: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Menno van der Elst, "Submission of an updated RMP version 2.0 in order to introduce changes to the design of the post-authorisation study STRIM-002 to reflect a change in the proposed RIS analysis methodology from SLiM-PCR to S-EPTS/LM-PCR and shifting the timelines." Opinion adopted on 28.05.2020, 20.05.2020.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Yescarta - axicabtagene ciloleucel - EMEA/H/C/004480/II/0021, Orphan,	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP

ATMP Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Anette Kirstine Stark, "Submission of a variation to update sections 4.2 and 4.4 of the SmPC to update the dose of tocilizumab to one dose instead of four doses in order to manage the Cytokine Release Syndrome. In addition, treatment centres should have access to an additional dose within 8 hours of each previous dose. Additional changes to the SmPC have been made with regards to the wording on GMO requirements. The Annex II, III, PL and RMP have been updated accordingly." Opinion adopted on 28.05.2020, 20.05.2020.	Members were in agreement with the CHMP recommendation.

B.5.7. PRAC assessed ATMP procedures

PRAC Led **Spherox - spheroids of human autologous matrix-associated chondrocytes - EMEA/H/C/002736/II/0016, ATMP** CO.DON AG, Rapporteur: Lisbeth Barkholt, CHMP Coordinator: Kristina Dunder, PRAC Rapporteur: Brigitte Keller-Stanislawski, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Update of the RMP to bring it in line with GVP Module V Rev. 2 template. The educational materials described in Annex II have been updated accordingly." Opinion adopted on 28.05.2020, 20.05.2020.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

B.5.8. Unclassified procedures and worksharing procedures of type I variations

WS1745 **Biktarvy-EMEA/H/C/004449/WS1745/0028** **Descovy-EMEA/H/C/004094/WS1745/0046** **Vemlidy-EMEA/H/C/004169/WS1745/0025** Gilead Sciences Ireland UC, Lead Rapporteur: Bruno Sepodes, "To update section 2 of the Product Information Annexes (PIs) of the medicinal products concerned, to align the pregnancy language between the summary of product characteristics (SmPC) and the patient information leaflet (PIL). In addition, the MAH has taken this opportunity	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

to: - Introduce an update to the sodium wording in section 6 of the PIL for Descovy, Biktarvy and Vemlidy. This update is in line with the excipient guidance. - Implement minor linguistic amendments (MLAs) for Descovy to the below languages: CS, ES, FI, MT, NL, NO, PT, RO, SV" Opinion adopted on 28.05.2020. Request for Supplementary Information adopted on 26.03.2020.	
WS1781/G **Infanrix hexa-EMEA/H/C/000296/WS1781/0272/G** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke Opinion adopted on 07.05.2020.	Positive Opinion adopted by consensus on 07.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1785/G **Infanrix hexa-EMEA/H/C/000296/WS1785/0274/G** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke Opinion adopted on 28.05.2020.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1787/G **M-M-RVAXPRO-EMEA/H/C/000604/ WS1787/0099/G** **ProQuad-EMEA/H/C/000622/WS1787/ 0140/G** MSD Vaccins, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 28.05.2020.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1788/G **Ambirix-EMEA/H/C/000426/WS1788/ 0106/G** **Cervarix-EMEA/H/C/000721/WS1788/ 0108/G** **Infanrix hexa-EMEA/H/C/000296/ WS1788/0273/G** **Twinrix Adult-EMEA/H/C/000112/ WS1788/0141/G** **Twinrix Paediatric-EMEA/H/C/000129/ WS1788/0142/G** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke Opinion adopted on 14.05.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1801 **Imatinib Teva-EMEA/H/C/002585/WS1801/0043**	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP

Teva B.V., Generic, Generic of Glivec, Lead Rapporteur: Maria Concepcion Prieto Yerro Opinion adopted on 28.05.2020.	recommendation.
WS1803 **Efficib-EMEA/H/C/000896/WS1803/0093** **Janumet-EMEA/H/C/000861/WS1803/0093** **Januvia-EMEA/H/C/000722/WS1803/0070** **Ristaben-EMEA/H/C/001234/WS1803/0062** **Ristfor-EMEA/H/C/001235/WS1803/0080** **TESAVEL-EMEA/H/C/000910/WS1803/0070** **Velmetia-EMEA/H/C/000862/WS1803/0096** **Xelevia-EMEA/H/C/000762/WS1803/0074** Merck Sharp & Dohme B.V., Lead Rapporteur: Johann Lodewijk Hillege, "To update section 4.4 of the SmPC and section 2 of the Package Leaflet to comply with the revised Annex to the European Commission guideline on "Excipients in the labelling and package leaflet of medicinal products for human use'." Opinion adopted on 28.05.2020.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1816 **Nuwiq-EMEA/H/C/002813/WS1816/0035** **Vihuma-EMEA/H/C/004459/WS1816/0017** Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 28.05.2020.	Request for supplementary information adopted with a specific timetable.
WS1818 **Rasilez-EMEA/H/C/000780/WS1818/0124** **Rasilez HCT-EMEA/H/C/000964/WS1818/0094** Noden Pharma DAC, Lead Rapporteur: Daniela Melchiorri Opinion adopted on 28.05.2020.	Positive Opinion adopted by consensus on 28.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

B.5.9. Information on withdrawn type II variation / WS procedure

WS1832 **HyQvia-EMEA/H/C/002491/WS1832/0058** **Kiovig-EMEA/H/C/000628/WS1832/0100** Takeda Manufacturing Austria AG, Lead Rapporteur: Jan Mueller-BerghausWithdrawal	The MAH withdrew the procedure on 22.05.2020.

request submitted on 22.05.2020.

B.5.10. Information on type II variation / WS procedure with revised timetable

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

B.6.1. Start of procedure for New Applications: timetables for information

idecabtagene vicleucel - EMEA/H/C/004662, Orphan, ATMP Celgene Europe BV, treatment of multiple myeloma	**Accelerated review**
tralokinumab - EMEA/H/C/005255 Treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy	
roxadustat - EMEA/H/C/004871 Treatment of anaemia	
pralsetinib - EMEA/H/C/005413 Treatment of non-small cell lung cancer (NSCLC)	
bevacizumab - EMEA/H/C/005433 Indicated in adults for the treatment of neovascular macular degeneration associated with aging and diabetes.	
azacitidine - EMEA/H/C/004761 Treatment for acute myeloid leukaemia	
remdesivir - EMEA/H/C/005622 Treatment of coronavirus disease 2019 (COVID-19)	
sitagliptin - EMEA/H/C/005598 Treatment of type 2 diabetes mellitus	
pegfilgrastim - EMEA/H/C/004780 Treatment of neutropenia	
sugammadex - EMEA/H/C/005403 Treatment of neuromuscular blockade induced by rocuronium or vecuronium	
tafasitamab - EMEA/H/C/005436, Orphan Morphosys AG, is indicated in combination with lenalidomide followed by monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), including DLBCL arising from low	

grade lymphoma, who are not eligible for, or refuse, autologous stem cell transplant (ASCT).

thiotepa - EMEA/H/C/005434
Conditioning treatment prior to haematopoietic progenitor cell transplantation (HPCT), treatment of solid tumours

B.6.2. Start of procedure for Extension application according to Annex I of Reg. 1234/2008): timetables for information

AUBAGIO - teriflunomide - EMEA/H/C/002514/X/0031/G
sanofi-aventis groupe, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, "1- Extension of a marketing authorisation for Aubagio to add the new strength, 7 mg film-coated tablet, for use in paediatric patients from 10 years of age and older with relapsing remitting multiple sclerosis (MS).
2- Type II (C.I.6) - Extension of indication to include treatment of paediatric patients aged 10 years and older with relapsing remitting multiple sclerosis (MS) for Aubagio 14 mg tablet. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance.

Version 6.0 of the RMP has also been submitted."
Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Bortezomib Accord - bortezomib - EMEA/H/C/003984/X/0023
Accord Healthcare S.L.U., Generic, Generic of VELCADE, Rapporteur: Milena Stain, PRAC Rapporteur: Amelia Cupelli, "Extension application to introduce a new pharmaceutical form associated with new strength (2.5 mg/ml solution for injection)."

Fabrazyme - agalsidase beta - EMEA/H/C/000370/X/0118/G
Genzyme Europe BV, Rapporteur: Johann Lodewijk Hillege

Ferriprox - deferiprone - EMEA/H/C/000236/X/0145
Chiesi Farmaceutici S.p.A., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Adrien

Inoubli, "Extension application to introduce a new pharmaceutical form (gastro-resistant tablets). The RMP (version 14.0) is updated in accordance."	
Maviret - glecaprevir / pibrentasvir - EMEA/H/C/004430/X/0033/G AbbVie Deutschland GmbH & Co. KG, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Ana Sofia Diniz Martins, "Extension application to introduce a new pharmaceutical form (50/20 mg coated granules in sachet), grouped with a type II extension of indication variation (C.I.6.a) to include the treatment of children from 3 to 12 years of age for the approved Maviret 100 mg/40 mg film-coated tablets; as a consequence, sections 4.1, 4.2, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated accordingly. Version 5.0 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.1."	
Nitisinone MDK - nitisinone - EMEA/H/C/004281/X/0007 MendeliKABS Europe Limited, Generic, Generic of Orfadin, Rapporteur: Alar Irs, PRAC Rapporteur: Amelia Cupelli, "Extension application to add a new strength of 20 mg (hard capsule)."	
Volibris - ambrisentan - EMEA/H/C/000839/X/0061/G GlaxoSmithKline (Ireland) Limited, Rapporteur: Maria Concepcion Prieto Yerro, Co-Rapporteur: Tomas Radimersky, PRAC Rapporteur: Eva A. Segovia, "Extension application to introduce a new strength (2.5 mg film-coated tablet), grouped with an extension of indication to include paediatric use (8 to less than 18 years). Version 9.0 of the RMP has been submitted. Type IA category A.7"	
Xerava - eravacycline - EMEA/H/C/004237/X/0009 Tetraphase Pharmaceuticals Ireland Limited, Rapporteur: Filip Josephson, PRAC Rapporteur: Adam Przybylkowski, "Extension application to add a new strength of 100 mg for eravacycline powder for concentrate for solution for infusion. The RMP (version 3.0) is updated in accordance. Additionally, the marketing authorisation holder	

took the opportunity to align the PI with the latest QRD template."

B.6.3. Restart of procedure - responses received to Day 120 List of Questions timetables: for information

belantamab mafodotin - EMEA/H/C/004935, Orphan
GlaxoSmithKline (Ireland) Limited, treatment of patients with relapsed or refractory multiple myeloma
List of Questions adopted on 28.04.2020.

meningococcal group a, c, w135 and y conjugate vaccine - EMEA/H/C/005084, Article 28
immunization against Neisseria meningitidis serogroups A, C, W-135 and Y
List of Questions adopted on 27.02.2020.

Pradaxa - dabigatran etexilate - EMEA/H/C/000829/X/0122/G
Boehringer Ingelheim International GmbH, Rapporteur: Mark Ainsworth, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Anette Kirstine Stark, "Extension application to add two new pharmaceutical forms for Pradaxa (coated granules (20 mg, 30 mg, 40 mg, 50 mg, 110 mg, 150 mg) and powder and solvent for oral solution (6.25 mg/ml)), grouped with:
-A type II variation (C.I.6.a) - Extension of indication to include new indication for Pradaxa 75 mg, 110 mg, 150 mg capsules based on the paediatric trials 1160.106 and 1160.108.
As a consequence, sections 4.1, 4.2, 4.3, 4.4, 4.5, 4.7, 4.8, 4.9, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. The RMP version 37.0 has also been submitted.
-Type IB (B.I.b.1.c)
-Type IA (B.I.b.1.b)
-Type IB (B.I.b.1.d)
-Type IA (B.I.b.2.a)
-Type IA (B.I.b.1.d)
-Type IA (B.I.d.1.a.1)
-Type IA (B.II.d.1.a)
-Type IB (B.II.d.1.d)
-Type IA (B.II.d.2.a)
-Type IA (B.II.c.1.c) "

List of Questions adopted on 27.02.2020.

rilpivirine - EMEA/H/C/005060
Treatment of human of human immunodeficiency virus type 1 (HIV-1)
List of Questions adopted on 12.12.2019.

influenza quadrivalent vaccine (rDNA) - EMEA/H/C/005159
Prevention of influenza disease
List of Questions adopted on 27.02.2020.

Trulicity - dulaglutide - EMEA/H/C/002825/X/0045
Eli Lilly Nederland B.V., Rapporteur: Martina Weise, PRAC Rapporteur: Ilaria Baldelli, "Extension application to introduce two new strengths of 3 mg and 4.5 mg solution for injection."
List of Questions adopted on 26.03.2020.

Ultomiris - ravulizumab - EMEA/H/C/004954/X/0004/G
Alexion Europe SAS, Rapporteur: Maria Concepcion Prieto Yerro, Co-Rapporteur: Agnes Gyurasics"Extension application to add a new strength (1100 mg in 11 ml vial, concentration 100 mg/ml) for Ultomiris concentrate for solution for infusion, grouped with a Type II application (B.II.z) for a new presentation including changes in the active substance concentration, excipients composition and concentrations, and minor differences in the last two steps of the manufacturing process."
List of Questions adopted on 30.04.2020.

cabotegravir - EMEA/H/C/004976
Treatment of Human Immunodeficiency Virus type 1 (HIV-1)
List of Questions adopted on 12.12.2019.

Xarelto - rivaroxaban - EMEA/H/C/000944/X/0074/G
Bayer AG, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, "Extension application to introduce a new pharmaceutical form, granules for oral suspension, 1 mg/ml. Extension of indication to include treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in term neonates, infants and toddlers, children, and adolescents aged less than 18 years following initiation of standard anticoagulation treatment for Xarelto 15 and 20

mg tablets.
As a consequence, sections 4.2, 4.4, 4.5, 4.8, 4.9, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly.
In addition, sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC is updated for all other dose strengths (2.5/10/ and 15/20 mg initiation packs) of Xarelto and corresponding sections of the Package Leaflet. Section 4.4 has been updated with regards to sodium content according to Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668).
The RMP version 12.1 has also been submitted."
List of Questions adopted on 30.04.2020.

B.6.4. Annual Re-assessments: timetables for adoption

B.6.5. Renewals of Marketing Authorisations: timetables for adoption provided only if the validation has been completed

Adcetris - brentuximab vedotin - EMEA/H/C/002455/R/0079, Orphan
Takeda Pharma A/S, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Menno van der Elst

Ervebo - recombinant vesicular stomatitis virus - Zaire ebolavirus vaccine (live) - EMEA/H/C/004554/R/0004
Merck Sharp & Dohme B.V., Rapporteur: Christophe Focke, PRAC Rapporteur: Menno van der Elst

NINLARO - ixazomib - EMEA/H/C/003844/R/0021, Orphan
Takeda Pharma A/S, Rapporteur: Daniela Melchiorri, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Annika Folin

B.6.6. VARIATIONS – START OF THE PROCEDURE

Timetables for adoption provided that the validation has been completed.

B.6.7. Type II Variations scope of the Variations: Extension of indication

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Abilify Maintena - aripiprazole -

EMEA/H/C/002755/II/0036/G
Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Bruno Sepodes

ADYNOVI - rurioctocog alfa pegol - EMEA/H/C/004195/II/0013
Baxalta Innovations GmbH, Rapporteur: Andrea Laslop

ADYNOVI - rurioctocog alfa pegol - EMEA/H/C/004195/II/0014/G
Baxalta Innovations GmbH, Rapporteur: Andrea Laslop

ADYNOVI - rurioctocog alfa pegol - EMEA/H/C/004195/II/0015/G
Baxalta Innovations GmbH, Rapporteur: Andrea Laslop

Dupixent - dupilumab - EMEA/H/C/004390/II/0031/G
sanofi-aventis groupe, Rapporteur: Jan Mueller-Berghaus

Epclusa - sofosbuvir / velpatasvir - EMEA/H/C/004210/II/0049/G
Gilead Sciences Ireland UC, Rapporteur: Filip Josephson

Fasenra - benralizumab - EMEA/H/C/004433/II/0028/G
AstraZeneca AB, Rapporteur: Fátima Ventura

Fasenra - benralizumab - EMEA/H/C/004433/II/0029/G
AstraZeneca AB, Rapporteur: Fátima Ventura

Flucelvax Tetra - influenza vaccine surface antigen inactivated prepared in cell cultures - EMEA/H/C/004814/II/0014
Seqirus Netherlands B.V., Rapporteur: Sol Ruiz

Fluenz Tetra - influenza vaccine (live attenuated, nasal) - EMEA/H/C/002617/II/0101
AstraZeneca AB, Rapporteur: Christophe Focke

Gardasil 9 - human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed) - EMEA/H/C/003852/II/0038/G
MSD Vaccins, Rapporteur: Kristina Dunder

Hizentra - human normal immunoglobulin - EMEA/H/C/002127/II/0116
CSL Behring GmbH, Rapporteur: Jan Mueller-

Berghaus

IDELVION - albutrepenonacog alfa - EMEA/H/C/003955/II/0041/G, Orphan
CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus

ILARIS - canakinumab - EMEA/H/C/001109/II/0069/G
Novartis Europharm Limited, Rapporteur: Jan Mueller-Berghaus

IMVANEX - smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/II/0047/G
Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus

IMVANEX - smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/II/0049
Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus

Inflectra - infliximab - EMEA/H/C/002778/II/0088/G
Pfizer Europe MA EEIG, Duplicate, Duplicate of Remsima, Rapporteur: Outi Mäki-Ikola

JETREA - ocriplasmin - EMEA/H/C/002381/II/0050
Oxurion NV, Rapporteur: Kristina Dunder

Keytruda - pembrolizumab - EMEA/H/C/003820/II/0088
Merck Sharp & Dohme B.V., Rapporteur: Daniela Melchiorri

Lamzede - velmanase alfa - EMEA/H/C/003922/II/0012/G, Orphan
Chiesi Farmaceutici S.p.A., Rapporteur: Johann Lodewijk Hillege

MabThera - rituximab - EMEA/H/C/000165/II/0173/G
Roche Registration GmbH, Rapporteur: Sinan B. Sarac

Menveo - meningococcal group a, c, w135 and y conjugate vaccine - EMEA/H/C/001095/II/0094/G
GSK Vaccines S.r.l, Rapporteur: Johann Lodewijk Hillege

Mysimba - naltrexone hydrochloride / bupropion hydrochloride -

EMEA/H/C/003687/II/0042
Orexigen Therapeutics Ireland Limited, Rapporteur: Mark Ainsworth

Nimenrix - meningococcal group a, c, w135 and y conjugate vaccine - EMEA/H/C/002226/II/0099/G
Pfizer Europe MA EEIG, Rapporteur: Bjorg Bolstad

Ongentys - opicapone - EMEA/H/C/002790/II/0028/G
Bial - Portela & Cª, S.A., Rapporteur: Martina Weise

Ontruzant - trastuzumab - EMEA/H/C/004323/II/0024/G
Samsung Bioepis NL B.V., Rapporteur: Koenraad Norga

Orencia - abatacept - EMEA/H/C/000701/II/0140/G
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Outi Mäki-Ikola

Pazenir - paclitaxel - EMEA/H/C/004441/II/0007
ratiopharm GmbH, Generic, Generic of Abraxane, Rapporteur: Milena Stain

Pergoveris - follitropin alfa / lutropin alfa - EMEA/H/C/000714/II/0068
Merck Europe B.V., Rapporteur: Mark Ainsworth

Perjeta - pertuzumab - EMEA/H/C/002547/II/0049/G
Roche Registration GmbH, Rapporteur: Sinan B. Sarac

Prevenar 13 - pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) - EMEA/H/C/001104/II/0190
Pfizer Europe MA EEIG, Rapporteur: Kristina Dunder

Privigen - human normal immunoglobulin - EMEA/H/C/000831/II/0163
CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus

ReFacto AF - moroctocog alfa - EMEA/H/C/000232/II/0153/G
Pfizer Europe MA EEIG, Rapporteur: Mark Ainsworth

Remsima - infliximab - EMEA/H/C/002576/II/0088/G
Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola

Respreeza - human alpha1-proteinase inhibitor - EMEA/H/C/002739/II/0041
CSL Behring GmbH, Rapporteur: Kristina Dunder

Revatio - sildenafil - EMEA/H/C/000638/II/0090/G
Upjohn EESV, Rapporteur: Johann Lodewijk Hillege

RoActemra - tocilizumab - EMEA/H/C/000955/II/0096
Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus
Opinion adopted on 14.05.2020.

Skyrizi - risankizumab - EMEA/H/C/004759/II/0010/G
AbbVie Deutschland GmbH & Co. KG, Rapporteur: Peter Kiely

Somavert - pegvisomant - EMEA/H/C/000409/II/0095
Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race

Stelara - ustekinumab - EMEA/H/C/000958/II/0080/G
Janssen-Cilag International NV, Rapporteur: Jayne Crowe

Taltz - ixekizumab - EMEA/H/C/003943/II/0034
Eli Lilly Nederland B.V., Rapporteur: Kristina Dunder

Trecondi - treosulfan - EMEA/H/C/004751/II/0003/G
medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Fátima Ventura

Trecondi - treosulfan - EMEA/H/C/004751/II/0004/G
medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Fátima Ventura

Vosevi - sofosbuvir / velpatasvir / voxilaprevir -

EMEA/H/C/004350/II/0040/G
Gilead Sciences Ireland UC, Rapporteur: Filip Josephson

Vyxeos liposomal - daunorubicin / cytarabine - EMEA/H/C/004282/II/0012/G, Orphan
Jazz Pharmaceuticals Ireland Limited, Rapporteur: Tuomo Lapveteläinen

Zinforo - ceftaroline fosamil - EMEA/H/C/002252/II/0052/G
Pfizer Ireland Pharmaceuticals, Rapporteur: Alar Irs

Zinplava - bezlotoxumab - EMEA/H/C/004136/II/0022
Merck Sharp & Dohme B.V., Rapporteur: Jan Mueller-Berghaus

WS1815/G
Hexacima-EMEA/H/C/002702/WS1815/0102/G
Hexaxim-EMEA/H/W/002495/WS1815/0107/G
Hexyon-EMEA/H/C/002796/WS1815/0106/G
Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus

WS1817/G
Infanrix hexa-EMEA/H/C/000296/WS1817/0276/G
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke

WS1823/G
Aflunov-EMEA/H/C/002094/WS1823/0060/G
Foclivia-EMEA/H/C/001208/WS1823/0055/G
Seqirus S.r.l, Lead Rapporteur: Daniela Melchiorri

WS1826
Ambirix-EMEA/H/C/000426/WS1826/0107
Twinrix Adult-EMEA/H/C/000112/WS1826/0142
Twinrix Paediatric-EMEA/H/C/000129/WS1826/0143
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke

WS1870/G
Entresto-EMEA/H/C/004062/WS1870/0033/G
Neparvis-EMEA/H/C/004343/WS1870/0030/G
Novartis Europharm Limited, Lead Rapporteur: Johann Lodewijk Hillege

B.6.9. CHMP assessed procedures scope: Non-Clinical and Clinical aspects

Aptivus - tipranavir - EMEA/H/C/000631/II/0085
Boehringer Ingelheim International GmbH, Rapporteur: Jean-Michel Race, "C.I.4: Update of section 4.5 of the SmPC in order to include a new interaction with Dolutegravir. The Product Leaflet has been updated accordingly."

Bexsero - meningococcal group B vaccine (recombinant, component, adsorbed) - EMEA/H/C/002333/II/0091
GSK Vaccines S.r.l, Rapporteur: Kristina Dunder, "Update of sections 4 of the SmPC in order to update the safety information and include Rash as Adverse Reaction in adolescents and adults. The Package Leaflet is updated accordingly."

Biktarvy - bictegravir / emtricitabine / tenofovir alafenamide - EMEA/H/C/004449/II/0032
Gilead Sciences Ireland UC, Rapporteur: Jean-Michel Race, "Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to update the efficacy and safety data in HIV-1 infected subjects aged ≥ 65 years based on week 48 interim results from study GS-US-380-4449, "A Phase 3b, Multicenter, Open-Label Study to Evaluate Switching from an Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide Fixed-Dose Combination Regimen or a Tenofovir Disoproxil Fumarate Containing Regimen to Fixed-Dose Combination of Bictegravir /Emtricitabine/Tenofovir Alafenamide in Elderly, Virologically-Suppressed, HIV-1 Infected Subjects Aged ≥ 65 Years"."

DaTSCAN - ioflupane (123i) - EMEA/H/C/000266/II/0059
GE Healthcare B.V., Rapporteur: Alexandre Moreau, "C.I.4, Update of sections 4.2 and 5.1 of the SmPC in order to describe the possibility

of quantitative reading in line with current scientific knowledge.”	
Dupixent - dupilumab - EMEA/H/C/004390/II/0032 sanofi-aventis groupe, Rapporteur: Jan Mueller-Berghaus, “Update of SmPC sections 4.8 and 5.1 based on results of a paediatric study report, LTS12551to fulfil the article 46 requirement (Regulation EC No 1901/2006). The LTS12551 study is an open–label extension study to evaluate the long-term safety and tolerability of dupilumab in patients with asthma.”	
Epidyolex - cannabidiol - EMEA/H/C/004675/II/0007, Orphan GW Pharma (International) B.V., Rapporteur: Mark Ainsworth, “Update of section 4.2 of the SmPC in order to add information regarding enteral administration using nasogastric and gastrostomy tubes.”	
Epidyolex - cannabidiol - EMEA/H/C/004675/II/0008/G, Orphan GW Pharma (International) B.V., Rapporteur: Mark Ainsworth, “Update of section 4.5 of the SmPC to reflect the data of the rifampicin drug-drug interaction study GWEP17074. Update of section 4.5 of the SmPC to reflect the data of the CYP1A2 substrate (caffeine) drug-drug interaction study GWCP18056. Update of sections 4.5 and 5.2 of the SmPC to propose an additional statement regarding the stiripentol interaction based on the pharmacological study GWEP1447 (provided in eCTD sequence 018, P46 006). Update of section 5.2 of the SmPC to reflect the data of the pharmacokinetic study GWEP17076, exploring the impact of meal, milk and alcohol on cannabidiol exposure. In addition, the MAH took the opportunity to correct the MAH address in the SmPC.”	
Infanrix hexa - diphtheria, tetanus, pertussis (acellular, component), hepatitis b (rdna), poliomyelitis (inact.) and haemophilus type b conjugate vaccine (adsorbed) - EMEA/H/C/000296/II/0275 GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke, “Update of sections 4.8 and 5.1 of the SmPC in relation to the frequency of adverse reactions somnolence and fatigue and	

to update the safety and immunogenicity information in infants and toddlers born to mothers vaccinated with dTpa during pregnancy; based on data generated from DTPA-048 and DTPA-049; these are phase IV, open-label, non-randomised, multicentre studies aimed to provide immunological responses to Infanrix hexa in terms of seroprotection status for diphtheria (D), tetanus (T), HBs antigen, inactivated poliovirus (IPV) and Haemophilus influenzae type b (Hib) antigens (PRP) and in terms of vaccine or booster responses to the pertussis antigens, 1 month after the last dose of the primary vaccination or the booster dose. The MAH took the opportunity to update the posology information in the package leaflet to align it with the SmPC. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.1."	
Juluca - dolutegravir / rilpivirine - EMEA/H/C/004427/II/0027 ViiV Healthcare B.V., Rapporteur: Janet Koenig, "Update of section 5.1 of the SmPC in order to add new information on resistance in vivo and clinical efficacy, based on final results from studies 201636 (SWORD-1) and 201637 (SWORD-2): Phase III, Randomized, Multicenter, Parallel-Group, Non-Inferiority Studies Evaluating the Efficacy, Safety, and Tolerability of Switching to Dolutegravir plus Rilpivirine from Current INSTI-, NNRTI-, or PI-Based Antiretroviral Regimen in HIV-1-Infected Adults who are Virologically Suppressed."	
Keytruda - pembrolizumab - EMEA/H/C/003820/II/0087/G Merck Sharp & Dohme B.V., Rapporteur: Daniela Melchiorri, "Update of section 5.1 of the SmPC in order to update efficacy information based on final results from three interventional efficacy studies in non-small cell lung cancer; study KEYNOTE-407 listed as a PAES in the Annex II, study KEYNOTE-189 listed as a category 3 study in the RMP and KEYNOTE-021 (cohort A, C and G1) listed as a category 3 study in the RMP."	
Kisplyx - lenvatinib - EMEA/H/C/004224/II/0035	

Eisai GmbH, Rapporteur: Bart Van der Schueren, "Submission of the final Clinical Study Report for Study E7080-J081-208 (Study 208), a Phase 2 Study of lenvatinib in Subjects with Advanced Thyroid Cancer."	
Lenvima - lenvatinib - EMEA/H/C/003727/II/0035/G Eisai GmbH, Rapporteur: Bart Van der Schueren, "-Submission of non-clinical final report from study M14014: Antiproliferative Activities of Lenvatinib Mesilate and Sorafenib Tosylate in VEGF-Stimulated Growth of HUVECs (human umbilical vein endothelial cells), relevant to the license's approved indications of differentiated thyroid cancer (DTC) and hepatocellular carcinoma (HCC) which were conducted since the approval of the initial Marketing Authorisation Application. -Submission of non-clinical final report from study M13015: Antiangiogenic Activity of Lenvatinib Mesilate and Sorafenib Tosylate in Human Papillary Thyroid Cancer Cell Line K1 Xenografts in Mice, relevant to the license's approved indications of differentiated thyroid cancer (DTC) and hepatocellular carcinoma (HCC) which were conducted since the approval of the initial Marketing Authorisation Application. -Submission of non-clinical final report from study M13016: Antiangiogenic Activity of Lenvatinib Mesilate and Sorafenib Tosylate in Human Follicular Thyroid Cancer Cell Line RO82-W-1 Xenografts in Mice, relevant to the license's approved indications of differentiated thyroid cancer (DTC) and hepatocellular carcinoma (HCC) which were conducted since the approval of the initial Marketing Authorisation Application. -Submission of non-clinical final report from study W-20140845: Antiangiogenic Activity of Lenvatinib Mesilate and Sorafenib Tosylate in bFGF-Induced Matrigel Plug Assay in Athymic Mice, relevant to the license's approved indications of differentiated thyroid cancer (DTC) and hepatocellular carcinoma (HCC) which were conducted since the approval of the initial Marketing Authorisation Application. -Submission of non-clinical final report from study on the Immuno-modulatory Activity of	

Lenvatinib Contributes to Antitumor Activity in the Hep1-6 Hepatocellular Carcinoma Model, relevant to the license's approved indications of differentiated thyroid cancer (DTC) and hepatocellular carcinoma (HCC) which were conducted since the approval of the initial Marketing Authorisation Application."

Lucentis - ranibizumab - EMEA/H/C/000715/II/0086

Novartis Europharm Limited, Rapporteur: Kristina Dunder, "C.I.11.b - Submission of the results of the second interim analysis (IA2) of the PAES study H2301E1"

Nerlynx - neratinib - EMEA/H/C/004030/II/0014/G

Pierre Fabre Medicament, Rapporteur: Bruno Sepodes, "Submission of the final reports from a safety pharmacology study evaluating the potential cardiovascular toxicity of a metabolite of neratinib maleate (report 20130869) and from a toxicology study evaluating the potential toxicity of another metabolite of neratinib maleate (Report 20104291)."

Nilemdo - bempedoic acid - EMEA/H/C/004958/II/0002

Daiichi Sankyo Europe GmbH, Rapporteur: Johann Lodewijk Hillege, "C.I.13: Submission of the final report from phase 2 study (1002FDC-058) listed as a category 3 study in the RMP. This is a randomized, double-blind, parallel Group Study to evaluate the efficacy and safety of the FDC (bempedoic acid 180 mg + ezetimibe 10 mg) compared to ezetimibe and placebo in subjects with type 2 diabetes and elevated LDL-Cholesterol."

Nustendi - bempedoic acid / ezetimibe - EMEA/H/C/004959/II/0002

Daiichi Sankyo Europe GmbH, Rapporteur: Johann Lodewijk Hillege, "C.I.13: Submission of the final report from phase 2 study (1002FDC-058) listed as a category 3 study in the RMP. This is a randomized, double-blind, parallel Group Study to evaluate the efficacy and safety of the FDC (bempedoic acid 180 mg + ezetimibe 10 mg) compared to ezetimibe and placebo in subjects with type 2 diabetes and elevated LDL-Cholesterol."

OFEV - nintedanib -
EMEA/H/C/003821/II/0033, Orphan
Boehringer Ingelheim International GmbH, Rapporteur: Peter Kiely, "Update of SmPC sections 4.8 and 5.1. to include additional clinical information from an open-label extension trial 1199.33 (INPULSIS-ON)"

OFEV - nintedanib -
EMEA/H/C/003821/II/0034, Orphan
Boehringer Ingelheim International GmbH, Rapporteur: Peter Kiely, "Update of section 5.1 of SmPC to include results of a double-blind, randomised, parallel-group trial to evaluate the efficacy and safety of Ofev co-administered with oral
sildenafil, compared to treatment with Ofev alone (INSTAGE Trial)."

Ovitrelle - choriogonadotropin alfa -
EMEA/H/C/000320/II/0081
Merck Europe B.V., Rapporteur: Paula Boudewina van Hennik, "Changes in sections 4.1, 4.2, 4.4 and 4.6 of the SmPC in order to update the terminology, in 4.3 to amend existing contraindications and in 4.8 to delete certain adverse drug reactions (ADRs) and add gastrointestinal ADRs with frequency common, with the aim to align the Product Information with similar text provided for other gonadotropin products.
The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.1 and performed minor linguistic changes."

Pergoveris - follitropin alfa / lutropin alfa -
EMEA/H/C/000714/II/0069
Merck Europe B.V., Rapporteur: Mark Ainsworth, "Submission of immunogenicity results on anti-drug antibodies (ADAs) against follicle stimulating hormone (FSH) and luteinizing hormone (LH), which were measured using validated assays in the bioequivalence study designed to compare the bioavailability of the liquid formulation to the previously-approved freeze-dried formulation (study EMR200061-006), as agreed during the assessment of the line extension application EMEA/H/C/714/X/47 (EC Decision received on 8 May 2017)."

Praxbind - idarucizumab -
EMEA/H/C/003986/II/0020
Boehringer Ingelheim International GmbH, Rapporteur: Jan Mueller-Berghaus, "C.I.4 Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to update information on paediatrics based on final results from study 1321.7. This was single dose, open label, uncontrolled, safety trial of intravenous administration of idarucizumab to paediatric patients enrolled from ongoing phase IIb/III clinical trials with dabigatran etexilate for the treatment and secondary prevention of venous thromboembolism listed as part of PIP (P46)."

Repatha - evolocumab -
EMEA/H/C/003766/II/0043
Amgen Europe B.V., Rapporteur: Johann Lodewijk Hillege, "C.I.4, Update of section 5.1 of the SmPC based on final results from study 20167869 (EVOPACS). It was a randomised, double-blind, placebo-controlled, multicenter study assessing the superiority of evolocumab vs. placebo administered during the acute phase of ACS (within 72 hours)."

Tafinlar - dabrafenib -
EMEA/H/C/002604/II/0045
Novartis Europharm Limited, Rapporteur: Filip Josephson, "Submission of the final report from study DRB436A2107 listed as a category 3 study in the RMP. This is a phase I, open label, multicenter, single dose study to evaluate the pharmacokinetics of dabrafenib in healthy subjects with normal hepatic function and subjects with impaired hepatic function."

Tafinlar - dabrafenib -
EMEA/H/C/002604/II/0046
Novartis Europharm Limited, Rapporteur: Filip Josephson, "Submission of the final report from study DRB436A2106 listed as a category 3 study in the RMP. This is a phase I, open label, multicenter, single dose study to evaluate the pharmacokinetics of dabrafenib in healthy subjects with normal renal function and subjects with impaired renal function."

Zinforo - ceftaroline fosamil -
EMEA/H/C/002252/II/0053
Pfizer Ireland Pharmaceuticals, Rapporteur: Alar Irs, "Update of sections 4.8 and 4.9 of the

SmPC in order to add eosinophilic pneumonia and encephalopathy as adverse drug reactions (ADRs), with frequencies 'not known' and 'uncommon' respectively, based on a review of the MAH global safety database and literature. The package leaflet is updated accordingly. In addition, the Marketing Authorisation Holder (MAH) clarified in section 4.8 of the SmPC that the ADRs agranulocytosis, neutropenia and eosinophilia have been identified post-marketing. Furthermore, the PI is brought in line with the latest QRD template version 10.1."

WS1842
Aluvia-EMEA/H/W/000764/WS1842/0113
Kaletra-EMEA/H/C/000368/WS1842/0185
Norvir-EMEA/H/C/000127/WS1842/0158
AbbVie Deutschland GmbH & Co. KG, Lead Rapporteur: Jean-Michel Race, "C.I.4: Change in section 4.8 of the SmPC in order to update the safety information for nephrolithiasis as an adverse reaction following an update to the Kaletra and Aluvia (lopinavir/ritonavir) and Norvir (ritonavir) Company Core Data Sheets (CCDS 0220). The Package Leaflet is updated accordingly.
In addition, the MAH/SOH takes the opportunity to make additional changes in the SmPC in order to comply with the current QRD template and provide clarity to instructions contained in the Package leaflet."

WS1845
Aluvia-EMEA/H/W/000764/WS1845/0114
Kaletra-EMEA/H/C/000368/WS1845/0186
Norvir-EMEA/H/C/000127/WS1845/0159
AbbVie Deutschland GmbH & Co. KG, Lead Rapporteur: Jean-Michel Race, "C.I.4: Change in section 4.5 of the SmPCs to update the safety information and include information on the interaction with fostamatinib following an update to the Kaletra and Aluvia (lopinavir/ritonavir) and Norvir (ritonavir) Company Core Data Sheets (CCDS 0419). The Package Leaflets are updated accordingly."

WS1846
Vfend-EMEA/H/C/000387/WS1846/0138
Pfizer Europe MA EEIG, Lead Rapporteur: Johann Lodewijk Hillege, "Update of section 4.5 of the SmPC in order to include additional text regarding interactions between voriconazole and

letermovir & tolvaptan in the interaction table. The Package Leaflet is updated accordingly."

WS1848
DuoPlavin-EMEA/H/C/001143/WS1848/0057
Iscover-EMEA/H/C/000175/WS1848/0143
Plavix-EMEA/H/C/000174/WS1848/0141
sanofi-aventis groupe, Lead Rapporteur: Bruno Sepodes, "To update sections 4.4 and 4.5 of the SmPC to add drug-drug interaction information for rifampicin and clopidogrel based on a literature review and a review of the MAH pharmacovigilance database. The package leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives and to update the SmPC for the excipient lactose in accordance with the Annex to the European Commission guideline on "Excipients in the labelling and package leaflet of medicinal products for human use". The MAH also took the opportunity to update the product information regarding the standard term for the all aluminium unit-dose blisters."

B.6.10. CHMP-PRAC assessed procedures

IDELVION - albutrepenonacog alfa - EMEA/H/C/003955/II/0042, Orphan
CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Menno van der Elst, "Update of section 4.2 of the SmPC to update the posology by expanding the once weekly routine prophylaxis regimen of Idelvion from 35-to 50 IU/kg to 25- to 50 IU/kg."

Myalepta - metreleptin - EMEA/H/C/004218/II/0012, Orphan
Amryt Pharmaceuticals DAC, Rapporteur: Bart Van der Schueren, PRAC Rapporteur: Adam Przybylkowski, "Update of section 4.4 of the SmPC in order to add a new warning on the risk of autoimmune disease following exposure to metreleptin; the Package Leaflet and the key elements to be included in the Guide/training material for healthcare professionals are updated accordingly. The RMP version 2.0 has also been submitted."

Privigen - human normal immunoglobulin - EMEA/H/C/000831/II/0161/G

CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski, "C.I.4: Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to amend an existing warning on haemolytic anaemia and to update safety information based on final results from study IgPro10_5003 listed as a category 3 study in the RMP; this is an observational hospital-based cohort study in the US to evaluate Privigen use and haemolytic anaemia in adults and children and the Privigen safety profile in children with CIDP; the Package Leaflet is updated accordingly. C.I.4: Update of sections 4.8 and 5.1 of the SmPC in order to update the list of adverse drug reactions based on final results from study IgPro10_3004; this is a Prospective Open-Label Single-Arm Study of the Pharmacokinetics and Safety of Intravenous IgPro10 in Japanese Subjects with Primary Immunodeficiency The RMP version 8.0 has also been submitted. In addition, the MAH took the opportunity to align the SmPC with the EU Core SmPC for IVIG, to update the local representative for Bulgaria in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.1."	
RoActemra - tocilizumab - EMEA/H/C/000955/II/0097 Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Update of section 4.2 of the SmPC for RoActemra 20 mg/mL concentrate for solution for infusion in order to amend the existing recommendations for monitoring of laboratory abnormalities in systemic juvenile idiopathic arthritis (sJIA) patients based on final results from study WA28029 (ARTHUR) listed as a category 3 study in the RMP; this is a Phase IV study to evaluate decreased dose frequency in sJIA who experience laboratory abnormalities during treatment with tocilizumab. The submission of the final study report for study WA28029 (ARTHUR) fulfils requirements of Article 46 of the paediatric regulation. The RMP version 26.0 has also been submitted. Changes to the RMP reflect the completion of study WA29029 (ARTHUR) and study WA22480 (ARTIS) which was assessed as part of variation EMEA/H/C/000955/II/0094."	

Trumenba - meningococcal group B vaccine (recombinant, adsorbed) - EMEA/H/C/004051/II/0027/G

Pfizer Europe MA EEIG, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Jean-Michel Dogné, "C.I.11.b- To update the RMP for Trumenba to version 4.0 to provide a revised protocol outline for study B1971060 in immunocompromised individuals: Although the study was originally designed to evaluate 3 doses of Trumenba administered on a 0-, 2-, and 6-month schedule, the MAH is now proposing a 2-dose regimen administered on 0- and 6-month schedule.
C.I.11.b- To submit the protocol outline for the co-administration study (C3511006). The MAH is proposing that the commitment to conduct a co-administration study with Trumenba may be met by a study of the MAH's candidate co-administered with MMR and PnC vaccines.
The date provided in the RMP for the submission of the protocols for these 2 studies ."

WS1844
Edistride-EMEA/H/C/004161/WS1844/0039
Forxiga-EMEA/H/C/002322/WS1844/0057

AstraZeneca AB, Lead Rapporteur: Kristina Dunder, Lead PRAC Rapporteur: Annika Folin, "Re-categorisation of the Forxiga/Edistride PASS (D169C00011): Retrospective Cohort Study on the Risk of Diabetic Ketoacidosis (DKA) to determine the effectiveness of additional risk minimization measures in place for DKA by assessing the impact of the risk minimisation measures on the risk of DKA in T1DM patients who are treated with dapagliflozin in Europe, from a category 1 to category 3 PASS in the RMP Version 20 and removal of the following Annex IID of the PI: Obligation to conduct the following Non-interventional PASS: In order to estimate the incidence of DKA in T1DM dapagliflozin users following implementation of RMMs in Europe, the MAH should conduct and submit the results from an observational cohort study using existing data sources in European countries where dapagliflozin will be launched for T1DM"

B.6.11. PRAC assessed procedures

PRAC Led

Duavive - estrogens conjugated / bazedoxifene - EMEA/H/C/002314/II/0025

Pfizer Europe MA EEIG, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Submission of the final clinical study report (CSR) for the Duavive Non-Interventional EU Drug Utilisation Study (DUS) - Study B2311061. This final CSR relates to the Post-Authorisation Measure MEA 003."

PRAC Led

Entyvio - vedolizumab - EMEA/H/C/002782/II/0050

Takeda Pharma A/S, Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "Variation to update the RMP with regards to the measures to evaluate effectiveness of additional risk minimization measures. The RMP update opportunity was used to add the completion date of the interim report for the post approval safety study (PASS) MLN00020401."

PRAC Led

Forsteo - teriparatide - EMEA/H/C/000425/II/0054

Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Adrien Inoubli, PRAC-CHMP liaison: Alexandre Moreau, "submission of the concluding report of the European Union (EU) component of the post-authorisation safety study (PASS): Study B3D-MC-GHBX(2.1) of Forsteo (teriparatide)."

Lucentis - ranibizumab - EMEA/H/C/000715/II/0085

Novartis Europharm Limited, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, "Submission of the results of the non-interventional post-approval efficacy and safety study OBTAIN"

PRAC Led

Neulasta - pegfilgrastim - EMEA/H/C/000420/II/0113

Amgen Europe B.V., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk

Hillege, "Submission of the final report from study 20160176 listed as a category 3 study in the RMP. This is a retrospective cohort study with primary outcome the time from index date to diagnosis of MDS or AML (safety)."

PRAC Led

Olumiant - baricitinib - EMEA/H/C/004085/II/0017

Eli Lilly Nederland B.V., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "C.I.13: Submission of the final report from Study I4V-MC-B010 "Rheumatologist Survey to Assess the Effectiveness of the Risk Minimisation Measures (RMM) for Olumiant" listed as a category 3 study in the RMP. This observational study was a multi-national cross-sectional survey. The RMP version 9.2 has also been submitted. In addition to the removal of this study from the RMP, three safety concerns (Use in combination with bDMARDs or with other JAK inhibitors, Use in patients with severe hepatic impairment, Effect on fertility, on pregnancy and the foetus, and use in breastfeeding) previously classified as Missing Information, have been removed from the list of safety concerns as per Procedure EMEA/H/C/004085/II/006."

PRAC Led

Shingrix - herpes zoster vaccine (recombinant, adjuvanted) - EMEA/H/C/004336/II/0031

GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke, PRAC Rapporteur: Sonja Hrabcik, PRAC-CHMP liaison: Andrea Laslop, "C.I.11.b To update the RMP for Shingrix to version 3.0 in order to present the outcome of the MAH assessment with respect to a potential increased risk of exacerbation of pre-existing pIMDs following vaccination with Shingrix. The implementation of the change is further substantiated by new additional data on post-hoc analyses and spontaneous reports of potential exacerbations of pIMDS from a worldwide safety database submitted by the MAH."

PRAC Led

Trulicity - dulaglutide - EMEA/H/C/002825/II/0051

Eli Lilly Nederland B.V., Rapporteur: Martina Weise, PRAC Rapporteur: Ilaria Baldelli, PRAC-CHMP liaison: Daniela Melchiorri, "Submission of the final study report for the PASS category 3 dulaglutide drug utilisation study B009: a multi-database collaborative research program of observational studies to monitor the utilisation and safety of dulaglutide in the EU (ref. PAM MEA 002-002.5). An updated RMP version 6.1 was provided as part of the application."

PRAC Led

Yervoy - ipilimumab - EMEA/H/C/002213/II/0080

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Submission of an updated RMP version 28.0 in order to propose the discontinuation of the Healthcare Professional Adverse Reaction Management Guide as an additional risk minimization measure described in the RMP Annex 6 and in the Product Information Annex II.D. The RMP and the annex II.D are updated accordingly. The MAH also took the occasion to align the PI to the latest QRD version 10.1 and to include standard text on sodium excipient information"

PRAC Led

WS1589

Incruse Ellipta-EMEA/H/C/002809/ WS1589/0029

Rolufta Ellipta-EMEA/H/C/004654/ WS1589/0014

GlaxoSmithKline (Ireland) Limited, Lead Rapporteur: Maria Concepcion Prieto Yerro, Lead PRAC Rapporteur: Ilaria Baldelli, PRAC-CHMP liaison: Daniela Melchiorri, "C.I.11.b. Submission of an updated RMP version 7.1 following completion of a category 3 study (WWE117397) "A Post-authorization safety Electronic Medical Records database retrospective cohort study of new users of inhaled UMEC/VI or new users of inhaled UMEC in the primary care setting". In addition, updates are included relating to the Category 1 study 201038 "A Post Authorisation Safety Observational Cohort Study to quantify the incidence of selected cardiovascular and cerebrovascular events in COPD patients using inhaled UMEC/VI combination or inhaled UMEC

versus Tiotropium" (EMEA/H/C/PSA/S/0032.3). The RMP is also updated to align with the Guidance on the Good Pharmacovigilance Practice (GVP) Module V - Risk management systems Revision 2 guidelines."

PRAC Led

WS1794

Brimica Genuair-EMEA/H/C/003969/ WS1794/0029

Duaklir Genuair-EMEA/H/C/003745/ WS1794/0029

AstraZeneca AB, Lead Rapporteur: Ewa Balkowiec Iskra, Lead PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "Submission of the final report from study D6570R00002 listed as a category 3 study in the RMP. This is a descriptive, non-interventional, multinational European cohort study of new users of aclidinium, aclidinium/formoterol, and other selected COPD medications. The RMP version 5.0 has also been submitted. As a consequence, the following safety concerns, listed as missing information in the RMP, are proposed to be remove: 'safety in patients with hepatic or severe renal impairment', 'safety in patients with benign hyperplasia or urinary retention' and 'use in pregnancy or lactation'."

PRAC Led

WS1795

Bretaris Genuair-EMEA/H/C/002706/ WS1795/0043

Eklira Genuair-EMEA/H/C/002211/ WS1795/0043

AstraZeneca AB, Lead Rapporteur: Ewa Balkowiec Iskra, Lead PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "Submission of the final report from study D6570R00002 listed as a category 3 study in the RMP. This is a descriptive, non-interventional, multinational European cohort study of new users of aclidinium, aclidinium/formoterol, and other selected COPD medications. The RMP version 5.0 has also been submitted. As a consequence, the following safety concerns, listed as missing information in the RMP, are proposed to be remove: 'safety in patients with hepatic or severe renal impairment', 'safety in patients with benign hyperplasia or urinary retention' and 'use in

pregnancy or lactation'."

PRAC Led
WS1805
Advagraf-EMEA/H/C/000712/
WS1805/0057
Modigraf-EMEA/H/C/000954/
WS1805/0035
Astellas Pharma Europe B.V., Lead Rapporteur: Jayne Crowe, Lead PRAC Rapporteur: Ronan Grimes, PRAC-CHMP liaison: Jayne Crowe, "Submission of an updated RMP version 3 in order to add a non-interventional post-authorization safety study related to the safety concerns of use during pregnancy and use during lactation. The two important potential risks, 'Exchangeability between the granule and capsule formulations of tacrolimus' for Modigraf and 'If administered accidentally either arterially or perivascularly, the reconstituted solution may cause irritation at the injection site' for Prograf concentrate for solution for infusion, are combined into the important identified risk 'Medication errors'. The RMP is being brought to EU RMP template revision 2."

PRAC Led
WS1850
Anoro Ellipta-EMEA/H/C/002751/
WS1850/0030
Laventair Ellipta-EMEA/H/C/003754/
WS1850/0033
GlaxoSmithKline (Ireland) Limited, Lead Rapporteur: Peter Kiely, Lead PRAC Rapporteur: Ilaria Baldelli, PRAC-CHMP liaison: Daniela Melchiorri, "To update the RMP completion of study WWE117397 "A Postauthorization safety Electronic Medical Records database retrospective cohort study of new users of inhaled UMEC/VI or new users of inhaled UMEC in the primary care setting." As part of the assessment of EMEA/H/C/WS1761 the MAH was requested to update the RMP.
In addition, the MAH has amendment the RMP with the study 201038 "A Post authorisation Safety Observational Cohort Study to quantify the incidence of selected cardiovascular and cerebrovascular events in COPD patients using inhaled UMEC/VI combination or inhaled UMEC versus Tiotropium" as approved during procedure EMEA/H/C/PSA/S/0032.3."

B.6.12. CHMP-CAT assessed procedures

Kymriah - tisagenlecleucel -
EMEA/H/C/004090/II/0025, Orphan,
ATMP
Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang

B.6.13. CHMP-PRAC-CAT assessed procedures

B.6.14. PRAC assessed ATMP procedures

B.6.15. Unclassified procedures and worksharing procedures of type I variations

WS1796/G
Aflunov-EMEA/H/C/002094/WS1796/
0059/G
Foclivia-EMEA/H/C/001208/WS1796/
0054/G
Seqirus S.r.l, Lead Rapporteur: Daniela Melchiorri

WS1806
Juluca-EMEA/H/C/004427/WS1806/0026
Tivicay-EMEA/H/C/002753/WS1806/0060
Triumeq-EMEA/H/C/002754/WS1806/
0081
ViiV Healthcare B.V., Lead Rapporteur: Filip Josephson

WS1809/G
Fluenz Tetra-EMEA/H/C/002617/
WS1809/0099/G
Pandemic influenza vaccine H5N1
AstraZeneca-EMEA/H/C/003963/
WS1809/0033/G
AstraZeneca AB, Lead Rapporteur: Christophe Focke

WS1812
Infanrix hexa-EMEA/H/C/000296/
WS1812/0277
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke,

WS1827
Keppra-EMEA/H/C/000277/WS1827/0188
UCB Pharma S.A., Lead Rapporteur: Koenraad Norga, "To update the PI following outcome of LEG-087. Section 4.4 of the SmPC: Special warnings and precautions for use was updated as follows:

- Addition of warning "seizure worsening" Section 4.8 Undesirable effects was updated as follows: - Addition of ADR "seizures aggravated" The PL was also updated accordingly. The requested worksharing procedure proposed amendments to the Summary of Product Characteristics and Package Leaflet.”	
WS1831 **Olanzapine Glenmark-EMEA/H/C/001085/WS1831/0033** **Olanzapine Glenmark Europe-EMEA/H/C/001086/WS1831/0030** **Olazax-EMEA/H/C/001087/WS1831/0026** Glenmark Arzneimittel GmbH, Generic, Generic of Olansek (SRD), Zyprexa, Zyprexa Velotab, Lead Rapporteur: Alexandre Moreau, “Update of section 4.8 of the SmPC to add salivary hypersecretion with a frequency of uncommon. The package leaflet is updated accordingly. In addition, the MAH has taken opportunity to correct Danish translation of pharmaceutical form for 'Olanzapine Glenmark Europe Orodispersible tablets' in this variation application.”	
WS1835 **Glyxambi-EMEA/H/C/003833/WS1835/0030** **Jentadueto-EMEA/H/C/002279/WS1835/0056** **Trajenta-EMEA/H/C/002110/WS1835/0042** Boehringer Ingelheim International GmbH, Lead Rapporteur: Johann Lodewijk Hillege	
WS1839/G **Hexacima-EMEA/H/C/002702/WS1839/0103/G** **Hexaxim-EMEA/H/W/002495/WS1839/0108/G** **Hexyon-EMEA/H/C/002796/WS1839/0107/G** Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus	
WS1841 **Ryzodeg-EMEA/H/C/002499/WS1841/0039** **Tresiba-EMEA/H/C/002498/WS1841/0045** **Xultophy-EMEA/H/C/002647/WS1841/0036**	

Novo Nordisk A/S, Lead Rapporteur: Kristina Dunder	
WS1843/G **Ebymect-EMEA/H/C/004162/WS1843/0048/G** **Xigduo-EMEA/H/C/002672/WS1843/0058/G** AstraZeneca AB, Lead Rapporteur: Kristina Dunder	
WS1847 **Nuwiq-EMEA/H/C/002813/WS1847/0036** **Vihuma-EMEA/H/C/004459/WS1847/0018** Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus, "To adapt SmPC, labelling and package leaflet and Annex II according to the currently valid Core SmPC guideline for human plasma derived and recombinant coagulation factor VIII products rev. 3 (EMA/CHMP/BPWP/1619/1999 Rev. 3). Moreover, the MAH took the opportunity to align the PI to QRD template version 10.1. In addition, more minor linguistic amendments like editorial changes in wording, typographical errors or punctuation mistakes were performed. Finally, section 4.4 of the SmPC and the PIL were updated in relation to sodium content following the Annex to the European Commission guideline on `Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668)."	
WS1855/G **Bretaris Genuair-EMEA/H/C/002706/WS1855/0044/G** **Eklira Genuair-EMEA/H/C/002211/WS1855/0044/G** AstraZeneca AB, Lead Rapporteur: Ewa Balkowiec Iskra	
WS1856/G **Brimica Genuair-EMEA/H/C/003969/WS1856/0030/G** **Duaklir Genuair-EMEA/H/C/003745/WS1856/0030/G** AstraZeneca AB, Lead Rapporteur: Ewa Balkowiec Iskra	
WS1860 **Aflunov-EMEA/H/C/002094/WS1860/0061**	

Foclivia-EMEA/H/C/001208/WS1860/
0057
Seqirus S.r.l, Lead Rapporteur: Daniela
Melchiorri

B.7. DOCUMENTS TABLED IN MMD AFTER THE CHMP PLENARY

B.7.1. Yearly Line listing for Type I and II variations

B.7.2. Monthly Line listing for Type I variations

B.7.3. Opinion on Marketing Authorisation transfer (MMD only)

B.7.4. Notifications in accordance with Article 61(3) of Council Directive 2001/83/EC (MMD only)

B.7.5. Request for supplementary information relating to Notification of Type I variation (MMD only)

B.7.6. Notifications of Type I Variations (MMD only)

C. Annex C - Post-Authorisation Measures (PAMs), (Line listing of Post authorisation measures with a description of the PAM. Procedures starting in that given month with assessment timetabled)

D. Annex D - Post-Authorisation Measures (PAMs), (Details on PAMs including description and conclusion, for adoption by CHMP in that given month, or finalised ones with PRAC recommendation and no adoption by CHMP needed)

E. Annex E - EMEA CERTIFICATION OF PLASMA MASTER FILES

Information related to plasma master files cannot be released at the present time as these contain commercially confidential information.

E.1. PMF Certification Dossiers:

E.1.1. Annual Update

E.1.2. Variations:

E.1.3. Initial PMF Certification:

E.2. Time Tables – starting & ongoing procedures: For information

PMF timetables starting and ongoing procedures	Tabled in MMD and sent by post mail (folder E).

F. ANNEX F - Decision of the Granting of a Fee Reduction/Fee Waiver

F.1. Parallel Distribution - Pursuant to Article 9 of Council Regulation (EC) No. 2743/98 of 14 December 1998, as amended

F.2. Request for scientific opinion on justification of exceptional circumstance and for imperative grounds of public health

G. ANNEX G

G.1. Final Scientific Advice (Reports and Scientific Advice letters):

Information related to Scientific Advice cannot be released at the present time as these contain commercially confidential information.

I Final Scientific Advice (Reports and Scientific Advice letters):

G.2. Ongoing procedures

G.3. PRIME

Some information related to PRIME cannot be released at the present time as these contain commercially confidential information.

G.3.1. List of procedures concluding at 25-28 May 2020 CHMP plenary:

Immunology-Rheumatology-Transplantation	
(SME)ATMP; Treatment of cerebral adrenoleukodystrophy where hematopoietic stem cell transplantation is indicated	The CHMP denied eligibility to PRIME and adopted the critical summary report.
Pneumology-Allergology	
(SME)Treatment of Loculated Pleural Effusions	The CHMP denied eligibility to PRIME and adopted the critical summary report.

G.3.2. List of procedures starting in May 2020 for June 2020 CHMP adoption of outcomes

H. ANNEX H - Product Shared Mailboxes – e-mail address